Physical Activity in People with COPD: the feasibility of a RCT to compare a physical activity intervention versus pulmonary rehabilitation, and the fidelity of the physical activity intervention

by

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Dissemination of Findings

O'Shea O.M, Bradley J.M, McDonough S.M, McGarvey L, Cosgrove D, Troosters T, Boyd A, McDonnell T, McManus T, O'Neill B. Patterns of physical activity in patients with chronic obstructive pulmonary disease (COPD) in Northern Ireland. Irish Thoracic Society Annual Scientific Meeting. Ir J of Med Sci (2015) Nov. Cork, Ireland. [Poster presentation]

O'Shea O.M, Bradley J.M, McDonough S.M, McGarvey L, Cosgrove D, Troosters T, Arden M, McDonnell T, McManus T, O'Neill B. Physical Activity in COPD: A clinician facilitated pedometer based walking programme. Irish Society of Chartered Physiotherapists Annual Conference Oct 2016. Wexford, Ireland. 184 (Suppl 11):S493 [Awarded best oral presentation]

O'Neill B, O'Shea O.M, McDonough S.M, McGarvey L, Bradbury I, Arden M, Troosters T, Cosgrove D, McManus T, McDonnell TJ, Bradley J.M. Physica**L** act**I**vity inter**V**ention v**E**rsus pu**L**monar**Y** rehabilitation in **COPD:** The **LIVELY COPD** Project. British Thoracic Society Winter Meeting Dec 2016. London, UK. 10.1136/thoraxjnl-2016-209333.39 [Oral presentation]

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Abstract

Background: People with COPD engage in lower levels of physical activity (PA) compared to healthy people. PA interventions (PAI) for people with COPD are not offered in the current healthcare system. **Aim:** To assess the feasibility of conducting a trial to explore the effectiveness a PAI versus pulmonary rehabilitation (PR) in improving physical activity in patients with COPD (the LIVELY COPD project); and to assess the treatment fidelity of the LIVELY PAI.

Methods: A mixed methods randomised controlled feasibility trial was undertaken and the treatment fidelity of the PAI was assessed. COPD patients referred to PR in two health and social care trusts were screened; n=50 were recruited and randomised. The PAI consisted of a 12 week pedometer driven walking intervention, participants had weekly contact with a physiotherapist/nurse and set step goals. Outcome measures were collected at baseline, post intervention and follow up. Qualitative interviews were conducted at post intervention. Based on a review of the literature, the Borrelli 2011 checklist was used to assess the fidelity of the PAI.

Results: N=50 participants were recruited (PAI n=23, PR n=27). There were less dropouts in the PAI (26%) compared to PR (52%). Participants in the PAI increased their average daily step count in line with the minimal clinically important difference for step count in COPD, this was not observed in PR. The results of the qualitative component demonstrated that the participants experienced a range of health benefits. Participants in both groups encountered barriers to participation; the PAI had a stronger emphasis on facilitators. The LIVELY PAI was delivered with good fidelity and the use of the Borrelli 2011 checklists provide a feasible platform for assessming fidelity of a PAI.

Conclusion: These findings support the feasibility of the LIVELY COPD project and there was important learning which could help ensure the success of a future trial. Testing the feasibility of a trial with a mixed methods design was a valuable process and the qualitative data enriched our results. Assessing the fidelity of the LIVELY PAI increased our understanding of the intervention. Future research is needed to test the intervention in a fully powered randomised controlled trial.

Abbreviations

AB	Adele Boyd
AMcD	Adrian McDonald
AR	Alanna Rogan
ATS	American Thoracic Society
BASES	British Association of Sport and Exercise Science
BCS	Behavioural Change Strategy
BHSCT	Belfast Health and Social Care Trust
BMI	Body Mass Index
BODEx index	Body mass index airflow Obstruction Dyspnea Exacerbations
BO'N	Brenda O'Neill
BTS	British Thoracic Society
CAT	COPD Assessment Test
CH	Catherine Hanratty
CI	Confidence Interval
COM-B	"capability" "opportunity" "motivation" "behaviour"
CONSORT	Consolidated Standards for Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
COREQ	Consolidated criteria for Reporting Qualitative studies
CPM	Counts Per Minute
CRF	Clinical Research Form
DC	Denise Cosgrove
DEL	Department of Employment and Learning
ERS	European Respiratory Society
FEV1%	Precent predicted Forced Expiratory Volume in 1 second
FEV1	Forced Expiratory Volume in 1 second
FVC	Forced Vital Capcity
GROC	Global Rating of Change
HCPs	Healthcare Professionals
HSC	Health and Social Care

IB	Ian Bradbury
IPAQ	International Physical Activity Questionnaire
ISWT	Incremental Shuttle Walk Test
JB	Judy Bradley
JW	Jason Wilson
LIVELY	physicaL actIvity VErsus puLmonarY rehabilitation in COPD
LLWCOPD	Living Well With COPD
LMcG	Lorcan McGarvey
MA	Madelynne Arden
MCID	Minimal Clinically Important Difference
MET	Metabolic Equivalent
MRC	Medical Research Council
MVPA	Moderate-Vigorous Physical Activity
NG	Natasha Greene
NHS	National Health Service
NI	Northern Ireland
NIH, BCC	National Institute for Health, Behavioural Change Consortium
NICHS	Northern Ireland Chest Heart and Stroke
NICRN	Northern Ireland Clinical Research Network
NIHR	Nationial Institute for Health Research
N=	Number equals
OO'S	Orlagh O'Shea
PA	Physical Activity
PAI	Physical Acitivity Intervention
PI	Principal Investigator
PR	Pulmonary rehabiliation
PRISMA	Preferred Reporting of Items for Systematic reviews and Meta Analyses
RMcC	Rosemary McCormick
RTC	Randomised Controlled Trial
SD	Standard Deviation

SMcD	Suazanne McDonough
SOC	Stages of Change
SPIRT	Standard Protocol Items: Recommendations for Interventional Trials
SPSS	Statsical Package for the Social Sciences
TIDieR	Template for Intervention Description and Replication
TMcD	Tim McDonnell
TMcM	Terry McManus
TREND	Transparent Reporting of Evaluations with Nonrandomised Designs
TT	Thierry Troosters
TTM	Transtheoretical model
UK	United Kingdom
VAS	Visual Analogue Scale
WHO	World Health Organisation
WHSCT	Western Health and Social Care Trust

Declaration

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Chapter 1 - Introduction

1.1 Introduction

This chapter will provide background information about the prevalence, presentation and treatment of chronic obstructive pulmonary disease (COPD). It will present evidence regarding the importance of physical activity (PA) for people with COPD and describe the levels of PA in the COPD population (Table 1.1 PA levels for different cohorts of people with COPD and healthy people). This chapter will also outline the importance of conducting and reporting on feasibility trials; the inclusion of a mixed methods research design within a feasibility trial, in addition to the relevance of assessing and monitoring treatment fidelity in the context of a feasibility trial. The aims and organisation of this thesis will also be outlined.

1.2 Chronic Obstructive Pulmonary Disease

COPD is a chronic and debilitating disease of the airways, characterised by irreversible airflow obstruction (GOLD 2017). This chronic airflow limitation is caused by changes in both the small airways and parenchymal destruction (emphysema) (GOLD 2017). These changes are caused by significant exposure to noxious gases, mainly smoking. Globally COPD is a highly prevalent cause of mortality and morbidity; it is currently the fourth leading cause of death worldwide; by 2020 it is estimated to be the third leading cause of death (Lozano et al. 2012). The increasing prevalence is due to the continued exposure to noxious gases and the ageing population in more developed countries (Mathers and Loncar 2006). The prevalence of COPD in the United Kingdom (UK) is estimated to be 2% (Snell et al. 2016). In Northern Ireland (NI) it is estimated that 1.8% of the population are living with COPD (DHSSPSNI 2013). However the actual prevalence of COPD is likely to be higher given that COPD is under diagnosed, particularly in the earlier stages of the disease (Soriano et al. 2009).

COPD is primarily a disease of the airways with some significant systemic (extrapulmonary) effects (GOLD 2017). These include renal and hormonal abnormalities, skeletal muscle dysfunction and anaemia and are due to the abnormal reaction in the systemic circulation (Palange 1998, GOLD 2017, John et al. 2005). Furthermore it is becoming increasingly recognised that these systemic effects as well as

the presence of other conditions can contribute to the increased severity of the disease (Vestbo et al. 2013). Some of the other comorbidities frequently reported in COPD patients include cardiovascular diseases, anxiety and/or depression and lung cancer (Hillas et al. 2015). The main symptoms of COPD include progressive breathlessness and chronic cough (GOLD 2017). These symptoms can be are managed through pharmacological and non-pharmacological treatment. Pharmacological treatment includes bronchodilators, corticosteroids and combination therapies, mucolytics and theophylline and in some cases oxygen therapy (NICE 2010). Non-pharmacological therapies include smoking cessation, non-invasive ventilation, surgery, nutrition and pulmonary rehabilitation (PR) (NICE 2010). PR can be defined as an interdisciplinary programme of care for patients with chronic respiratory impairment that is individually tailored and designed to optimise each patient's physical and social performance as well as their autonomy; programmes comprise of individualised exercise programmes and education (Bolton et al. 2013). PR has been shown to increase exercise capacity and quality of life in people with COPD (McCarthy et al. 2015). Exercise training and education are the key components of the treatment of PR. Individuals with COPD tend to avoid activities that induce breathlessness (Katajisto et al. 2012, Todt et al. 2015); these can be simple activities of daily living for example washing and dressing. Lower levels of activity have been observed in the early stages of the disease process (Watz et al. 2009) which decreases further with increasing disease severity (Troosters et al. 2010a). PR is currently the only form of exercise training available within the health service for people with COPD.

The British Thoracic Society (BTS) guidelines recommend that PR programmes are delivered for a minimum of 6 weeks (6-12 weeks) with two weekly supervised exercise sessions and a third session unsupervised (Bolton et al. 2013). It is recommended that a combination of progressive muscle resistance and aerobic training should be delivered for the exercise training and there are 20 recommended educational topics in the BTS guidelines (Bolton et al. 2013). Qualitative research with COPD patients and health professionals has identified six key topics that they perceived as important for inclusion in the education component of PR (Wilson et al. 2007). PR is part of the standard treatment of COPD and there is a strong evidence base to support this; PR has been shown to not only improve exercise capacity and quality of life (McCarthy et al. 2015), it has also been shown to reduce exacerbations (Gruel et al. 2000), hospital admissions as well

as length of stay (Griffiths et al. 2001). Despite this evidence, a recent audit in PR for England and Wales has demonstrated that PR does not seem to suit all patients with COPD; not all patients referred to PR attend for assessment and not all patients who are assessed enroll in the programme (Steiner et al. 2016). Furthermore dropout rates for PR for those patients who enroll in PR have been reported to be as high as 50% (Chaplin et al. 2017); data from a recent audit of PR in England and Wales reported a dropout rate of 29% (Steiner et al. 2016). Finally PR does not always result in increased PA (Spruit et al. 2013, Bolton et al. 2013).

1.3 Physical Activity and COPD

PA is defined as any bodily movement produced by skeletal muscles that results in energy expenditure (Casperson et al. 1985, WHO 2017). Exercise is a subset of PA that is planned, structured, and repetitive and has as a final or an intermediate objective the improvement or maintenance of physical fitness (Casperson et al. 1985). Regular PA is associated with improved health outcomes in relation to the prevention of several chronic disease and premature death (Warburton et al. 2006). The British Association of Sport and Exercise Science (BASES 2011) have devised PA guidelines to clarify the minimum amount of PA that people should engage in to maintain good health. These guidelines recommend that adults should engage in three core activities; aerobic activity, strength training and reduce time spent sitting/lying. The guidelines state that healthy individuals should be active on every day of the week; this activity should add up to 150 minutes of moderate activity or 30 minutes on at least 5 days of the week with at least two days of muscle strength training. With regards to aerobic activity, comparable benefits can be achieved through 75 minutes of vigorous activity spread across the week: or in combinations of moderate and vigorous activity. Aerobic activity should be completed in bouts of ten minutes; during moderate activity individuals should feel their heart beat faster and still be able to maintain a conversation whilst in vigorous activity their heart would beat more rapidly, therefore making it difficult to carry out a conversation. Daily PA can also be completed in terms of step count. Current guidelines recommend 10000 steps per day for healthy adults (Tudor –Locke and Bassett 2004); walking at approximately 100 steps per minute represents moderate activity (Tudor-Locke et al. 2005)

People with COPD engage in lower levels of PA than healthy individuals (Pitta et al. 2005). The COPD population included in this study engaged in a mean (standard deviation (SD)) of 44(26) minutes of walking per day compared to 81(26) minutes completed by healthy people. Tudor-Locke et al. (2011) have recommended that individuals living with a disability and/or chronic illness, including people with COPD, complete 7000-8000 steps per day. The PA levels of patients with COPD can vary depending on country (Table 1.1). The studies contained in Table 1.1 contain small numbers which prevent any firm conclusions regarding the daily PA levels of people with COPD in these countries, but however do give us some representation of the varying levels of daily PA in people with COPD and how they compare with healthy adults. A recent meta-analysis demonstrated that individuals with COPD complete on average 4,579 steps per day and their PA levels are mainly influenced by disease severity (Saunders et al. 2016). As observed in healthy populations, PA plays an important role in the maintenance of health in people with COPD (Min Lee and Skerret 2001); Higher levels of PA are associated with better COPD outcomes in terms of reduced exacerbations, hospitalisations and mortality (Garcia-Aymerich et al. 2006, Moy et al. 2013, Gimeno-Santos et al. 2014). Given the research indicating the importance of PA in people with COPD, there has been a focus on interventions to increase PA in this population. PR is currently the only form of exercise training offered to people with COPD within the health service and it does not always result in increased PA (Spruit et al. 2013).

Waschecki et al. (2011) have reported that objectively measured PA is the strongest predictor of all-cause mortality in people with COPD. PA can be objectively measured in COPD using a number of different devices. A recent review by Byron and Rowe (2016) identified the five most commonly used devices to measure PA in the COPD literature: (i) The SenseWear Armband device (ii) The DynaPort Activity Monitor, (iii) The ActiGraph 7164, GT1Mand GT3X+devices (iv)The RT3 Tracker and (v) the Yamax Digiwalker. All of these devices are accelerometers except for the Yamax Digiwalker which is a pedometer. In an exploration of the validity of activity monitors in people with COPD; the ActiGraph GT3x. DynaPort and SenseWear armband have been identified as the most valid monitors during standardised activities (Van Remoortel et al. 2012).

There is some existing literature exploring different platforms for delivering PR and PA training to people with COPD. For PR, researchers have compared unsupervised home based PR with traditional PR (Holland et al. 2016), web based PR programme with traditional PR (Chaplin et al. 2017) and once weekly supervised versus twice weekly supervised PR (O'Neill et al. 2007). In general results of these different programmes still showed short to medium term benefit comparable with traditional PR. In terms of PA training, interventions have varied in terms of the type of PA, frequency, duration and components included (Wilson et al. 2014). For example Behnke et al. 2005 compared a 10 day hospital based walking programme, consisting of five, 15 minute walking sessions per day with a control group (did not received any training). Elsewhere Pomidoiri et al. 2012, compared a low intensity calisthenics and breathing programme with a high intensity whole body endurance and strength programme, both programmes consisted of one hour training, three times per week for 12 weeks. These interventions showed favourable effects. However, no previous research has compared a PAI to PR in people with COPD. The effectiveness of a PAI, compared to PR at increasing PA in people with COPD is unknown.

The review by by Wilson et al. 2014 was available at the outset of this Thesis and as such was used to inform the rationale for the PA intervention. In Wilson et al. (2014) eight of the twenty articles included were solely walking based interventions (Behnke et al. 2005, Wewel et al. 2008, Hospes et al. 2009, Breyer et al. 2010, Moy et al. 2010, Pomidori et al. 2012, Moy et al. 2012, Pleguezuelos et al. 2013). More recent publications have also explored the effectiveness of PAIs in people with COPD (Moy et al., 2015, Altenburg et al. 2015, Demeyer et al. 2017). Although these publications were not available at the outset of this thesis it is reassuring that they too have included many of the suggestions from Wilson et al. 2014; they also focused on walking. For example the study by Demeyer et al. 2017compared a 12 week semiautomated 12 week telecoaching programme with usual care (no intervention). The intervention group received a step counter and exercise booklet, weekly step goals were automatically generated based on local weather reports and each patients current PA levels. Participants in this intervention demonstrated improvements in PA and exercise capacity.

Step count is a simple and understandable metric of PA and walking represents a form of PA that does not require any formal training or specialist equipment and can be

undertaken in an individual's own time and environment (Tully et al. 2007) and is necessary for activities of daily living. More recently the use of a pedometer for self-monitoring has been identified as a successful strategy for promoting adherence and increasing PA in PAIs for people with COPD (Mantaoni et al. 2016, Leidy et al. 2014)

1.4 Feasibility trials

In recent years the role of feasibility studies has gained increased attention (Lancaster 2015). Feasibility studies are pieces of research conducted before a main study in order to answer the question 'Can this study be done?' (NIHR 2012). The main reasons for conducting a feasibility study can be grouped into four main classifications: (i) process; this refers to recruitment and retention rates, (ii) resource; deals with time and any budget problems, (iii) management; this explores personnel and data management issues and (iv) scientific; assesses treatment safety, determination of dose levels and response and estimation of treatment effect and its variance (Thabane et al. 2010). Despite the importance of conducting a feasibility trial there is an inconsistency in the literature regarding the reporting of feasibility trials. The National Institute for Health Research (NIHR 2012) has published criteria to determine the success of conducting a feasibility trial and these can be used to guide the reporting of such studies. More recently, Thabane et al. (2016) have published a proposed extension to the Consolidated Standards of Reporting Trials (CONSORT) statement for the reporting of feasibility and pilot studies. According to Thabane et al. (2010) the most frequent mistake made in the conduct of feasibility trials is that researchers place an emphasis on effectiveness as an outcome.

The use of both quantitative (descriptive) and qualitative analysis has been recommended in feasibility trials (Tickle-Degnen 2012, O'Cathain 2015, Craig et al. 2006). Obtaining participants' views within a feasibility trial can help determine the acceptability of different aspects of the trial including for example the intervention itself and outcome measures. Acceptability of the intervention is a key criterion of feasibility. Furthermore conducting mixed methods research has been advocated within physiotherapy research (Shaw et al. 2010). Physiotherapy as a profession aligns both subjective and objective assessments to help determine treatment and diagnosis; mixed methods research is therefore well placed within physiotherapy research. Rauscher and Greenfield (2009) proposed three different designs for mixed methods research: (i) the quantitative research is conducted first followed by the qualitative research to explain the quantitative results

(ii) the qualitative research is conducted first to help inform how the intervention or quantitative data will be collected and (iii) the quantitative and qualitative research are conducted simultaneously throughout the research process, both the quantitative and qualitative research are addressing the same research question; the third method is the most applicable for a feasibility trial, as the quantitative and qualitative data are addressing the same research question.

Another key purpose of conducting feasibility trials is to reduce threats to the validity of the study's outcomes (Tickler-Degnan 2012). Validity can be defined as both internal and external. Internal validity ensures that the results of the intervention are attributable to the intervention and no extra treatment factors (Moncher and Prinz 1991). External validity enhances the replicabliltiy of the intervention, for example, if the intervention was to be repeated in a full RTC then the same - if not similar - results would be expected (Moncher and Prinz 1991). Treatment fidelity, although a concept that is often neglected in the literature (Borrelli et al. 2005), has been identified as important in maintaining the validity of a trial. Treatment fidelity can be defined as the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions. It also refers to the methodological practices used to ensure that a research study reliably and validly tests a clinical intervention (Bellg et al. 2004). In short; treatment fidelity ensures that the intervention is delivered as intended (Bellg et al. 2004).

1.5 Summary

COPD is a preventable and treatable yet incurable disease. PA levels are low among the COPD population (Troosters et al. 2010a). Despite the established benefits of PA in people with COPD there are no interventions specifically targeted at increasing PA in this population offered within the health service. However, research has demonstrated that PAIs can increase PA in people with COPD, and walking interventions are frequently used in this population (Wilson et al. 2014). A pedometer driven walking intervention may have the capacity to increase PA in people with COPD compared to PR. It could also offer an alternative to PR allowing for increased choice for patients with COPD.

Recent publications have highlighted the need to conduct and report on feasibility trials (Thabane et al. 2016). Before investigating a PAI and comparing a PAI to PR in a full scale randomised controlled trial (RTC) it is necessary to test the feasibility of conducting

the trial. Testing the feasibility of a trial in a mixed methods design will provide important information regarding the acceptability of the trial (Cooper al. 2014). Finally the assessment and monitoring of treatment fidelity has the potential to reduce any threats to the validity of a proposed trial, it is therefore an important element to include (Bellg et al. 2004).

1.6 Aims and organisation of this thesis

1.6.1 Aims and organisation of thesis

There were two key aims of this thesis. Firstly, to assess the feasibility of conducting a trial to explore the effectiveness of a pedometer driven clinician facilitated PAI versus PR in improving PA in COPD patients referred to PR (the LIVELY COPD project); and secondly, to assess the treatment fidelity of the LIVELY PAI. In order to achieve these aims, a mixed methods randomised controlled feasibility trial was undertaken and the treatment fidelity of the PAI was assessed. These aims have informed the chapters within this PhD, each chapter has its own unique objectives.

1.6.2 Organisation of thesis

Chapter 2 details the methods used for the LIVELY COPD project. This includes a description of the procedures used for screening, recruitment, randomisation and the assessment tools used (for example: questionnaires, activity monitors, the incremental shuttle walk test) and also details the elements included in the PAI and PR.

Chapter 3 describes the quantitative component of the LIVELY COPD project which examined the feasibility of exploring the effectiveness of PAI versus PR in improving PA in COPD patients referred to PR. This chapter utilises the NIHR (2012) criteria for success of a feasibility study to assess the feasibility of the trial as a whole as well as guidance from other current literature to assess the feasibility of the PAI, specifically (Paxton et al. 2017).

Chapter 4 describes the qualitative component of the LIVELY COPD project, the methods employed and the results of the qualitative component of the LIVELY COPD project are reported.

Chapter 5 details a scoping review conducted to identify how treatment fidelity is defined and to explore the extent to which the reported fidelity is assessed/monitored in the published literature on behaviour change, physiotherapy, physical activity interventions

and exercise therapy and how the methods employed in this literature map to the five domains of treatment fidelity as set out by the National Institute for Health, Behaviour Change Consortium (NIH BCC) (Bellg et al. 2004).

Chapter 6 describes the development of a framework to assess the treatment fidelity of the LIVELY COPD project using the Borrelli (2011) checklist. This chapter also includes the results of the assessment of treatment fidelity of the LIVELY PAI.

Chapter 7 summarises the main research findings and outputs from the research conducted in the current thesis. The implications and recommendations for future research and practice are also discussed.

1.6.3 Roles of research team and financial support

This PhD was funded by the Department of Employment and Learning (DEL) and fully embedded in the LIVELY COPD project which was funded by Northern Ireland Chest Heart and Stroke (NICHS). The protocol for the LIVELY COPD project was developed by Dr Brenda O'Neill (BO'N) (Chief Investigator), Professor Judy Bradley (JB), Professor Suzanne McDonough (SMcD), Dr Lorcan McGarvey (LMcG) (local Principal Investigator (PI), Belfast Health and Social Care Trust (BHSCT)), Dr Terence McManus (TMcM) (local PI, Western Health and Social Care Trust (WHSCT)), Professor Thierry Troosters (TT), Professor Madelynne Arden (MA), Dr Ian Bradbury (IB), Dr Tim McDonnell (TMcD), Dr Denise Cosgrove (DC). The LIVELY COPD project was supported by the Northern Ireland Clinical Research Network (NICRN), respiratory health and the PAI was delivered by network coordinators (DC, CH and AMcD). My primary role within the LIVELY COPD project was (i) data collection; assessing patients with the outcome measures at each time point (methods are outlined in Chapter 2); This involved liaising with the network staff delivering the PAI and those delivering PR, (ii) data input and analysis; all outcome measure data collected was inputted into Statistical Package for Social Sciences (SPSS) version 22.0 (SPSS Inc., Chicago, IL) for analysis, (iii) conducting and analysing the qualitative component and (iv) the development and implementation of the protocol for the assessment of fidelity of the PAI.

For each of the chapters/studies different members of the research team were involved or had more prominent roles and Chapter 5 was conducted in collaboration with a master's student (RMcC). The researchers involved and the roles of each of the members of the research team are outlined at the beginning of each chapter.

Table 1-1Physical Activity levels for different groups of people with COPD and healthy people

Study	Population	N=	Device used	Results		
Wilson 2014**	Northern Ireland (healthy adults)	N=30	ActiGraph GT3X	Light PA (mins/day)	MVPA (mins/day)	Daily steps
				236 (59)	35 (20)	7,802 (2,574)*
Troosters et al. 2010a**	Belgium (COPD)	N=20	SenseWear Pro Armbands	Mild (mins/day)	Moderate (mins/day)	Daily steps
				93(15)	27(7)	6383 (643)
	Belgium (healthy adults)	N=30	SenseWear Pro Armbands	160(89)	65 (70)	9372 (3574)
	Italy (COPD)	N=29	SenseWear Pro Armbands	64(18)	10(8)	6610 (804)
	USA (COPD)	N=21	SenseWear Pro Armbands	62(15)	21(7)	5115 (675)
Park et al. 2013**	USA (healthy adults)	N= 1386	ActiGraph	Light PA (mins/day)	MVPA (mins/day)*	
				288.06 (101.53)	12.21 (26.23)	
Egan et al. 2012	Republic of Ireland (COPD)	N=46	SenseWear Pro Armbands	Daily Physical activity duration in minutes		Daily steps
				48.0 (66.8)		3611 (2863)

*MVPA: moderate to vigorous physical activity ** Results are mean (SD)

Chapter 2 - Methods

2.0 Chapter overview

The LIVELY COPD project (Chapter 3) was designed to assess the feasibility of conducting a trial to investigate the effectiveness of a PAI (physical activity consultation and a pedometer-based walking programme) versus PR in improving PA in COPD. This general methods chapter will detail the LIVELY PAI, outline the procedures followed for the outcome measure assessment for the LIVELY COPD project, data collection and will describe the development of the study materials for the LIVELY COPD project. The role of each of the members in the study team is outlined in Table 2.1.

Table 2-1 Role of members of study team

Personnel	Role
Orlagh O'Shea	-Preparation and updating of study materials -Conducting and scheduling outcome measures assessments -Data entry, data checking and data cleaning -Analysis of results -Write up of methods
Dr. Brenda O'Neill	-Development of the LIVELY PAI -Preparation and updating of study materials - Selection of outcome measures -Development of clinical research record forms -Training of staff for outcome measure assessment -Training of providers to deliver the PAI -Conducting outcome measure assessment (back up for annual leave) -Analysis of results -Intellectual contribution to and write up of chapter
Prof. Judy Bradley	-Development of the LIVELY PAI - Selection of outcome measures -Development of clinical research record forms -Training and mentoring of providers to deliver the PAI -Analysis of results -Intellectual contribution to and write up of chapter
Prof. Suzanne McDonough	-Development of the LIVELY PAI -Selection of outcome measures -Development of clinical research record forms -Training and mentoring of providers to deliver the PAI -Analysis of results -Intellectual contribution to and write up of chapter
Dr. Adele Boyd	-Preparation and updating of study materials

	-Conducting and scheduling outcome measures assessment -Data entry
Dr Denise Cosgrove	-Screening of patients for the LIVELY COPD project -Participation in training to deliver the PAI -Delivery of the LIVELY PAI
Dr Catherine Hanratty	-Screening of patients for the LIVELY COPD project -Participation in training to deliver the PAI -Delivery of the LIVELY PAI -Data entry
Adrian McDonald	-Screening of patients for the LIVELY COPD project -Participation in training to deliver the PAI -Delivery of the LIVELY PAI
Dr Terence McManus	-PI for the WHSCT
Dr Lorcan McGarvey	-PI for the BHSCT
Prof Madeline Arden	-Development of the LIVELY PAI
Prof Thierry Troosters	-Development of the LIVELY PAI
Dr Tim McDonnell	-Development of the LIVELY PAI
Dr Jason Wilson	-ActiGraph data analysis training -Objective PA data checking and cleaning

2.1 Introduction

Complete reporting of RCTs is important to allow for accurate assessment and replicability of the methodology and findings of the trial (Schulz et al. 2010, Hoffman et al. 2014). Therefore the aim of this chapter is to outline the general methods of the administration and analysis of the assessment tools and to assess the outcome of the intervention (PAI) and the comparative condition (PR). The assessment tools are described with reference to the published guidance and recommendations in addition to the evidence of reliability and validity for each tool where available. This chapter also aims to describe the PAI and PR and the study materials for the LIVELY COPD project.

2.2 Study Design and Study procedures

A randomised controlled mixed methods design was used in this trial. Participants were randomised to ensure that the allocation of patients in this trial was not biased by baseline status. A feasibility RCT was conduted to help inform a future trial. Patients attended four study visits for outcome assessment. The baseline assessment was conducted over two appointments 7 days apart (Visit 1 and 2). Participants were randomised to either group (PAI or PR) following baseline assessment. The summary the outcome measures used is available in Table 2.2. The LIVELY COPD project was testing the feasibility of a PAI versus PR in improving PA in people with COPD, therefore PA was a key outcome

measure of the current study. The selection of measures for the assessment of PA were based on recent research on PA monitors in COPD and the respiratory population (Van Remoortel et al. 2012, Bradley et al. 2015) PR has been proven to increase exercise capacity and quality of life, therefore exercise capacity and quality of life measures were included (McCarthy et al 2015); the CAT and ISWT are routinely used in PR to assess these variables (Steiner et al. 2015). Participants were assessed again post-intervention (Visit 3) and at 3 months following the end of the intervention (Visit 4). All data collected in this study was inputted and analysed in Statistical Package for the Social Sciences (SPSS) version 22.0.0 for Windows (SPSS Inc Chicago IL. USA), unless otherwise detailed. Data was inputted into SPSS by AB, OO'S and CH. All data inputted into SPSS was checked by BO'N and JB, unless otherwise described in the methods.

2.2.1 Baseline demographics

All patients who had been screened and expressed an interest in participating in the study were approached at the PR assessment clinic, where informed consent was obtained (Appendix 1, LIVELY Clinical Research Form (CRF) Instructions, Screening and Recruitment Process page 5, 6 on CD-ROM). Once informed consent had been obtained a range of demographic information was obtained from the participant, including age, date of birth, smoking history, whether they were on long term oxygen therapy, their resting SpO_2, living arrangements, work status/history, previous attendance at PR, medical history, comorbidities and medications (respiratory and non-respiratory). Further information was obtained from the PR assessment team notes; including spirometry, height and weight which was used to calculate their body mass index (BMI). This information was recorded in the case report form (Appendix 2, LIVELY CRF, page 5, 6 and 8, on CD ROM)

2.2.2 Outcome measure data collection

2.2.2.1 Medical Research Council (MRC) Breathlessness Scale

The MRC breathlessness scale (Appendix 2, LIVELY CRF, page 7, on CD-ROM) is a subjective measure of disability as result of shortness of breath in respiratory populations (Fletcher et al. 1959). The MRC breathlessness scale was conducted at baseline only. Patients chose a rating of their breathlessness on a five point scale (Grade 1 to Grade 5).

Grade 1 represents the least amount of disability as a result of shortness of breath ("not troubled by breathlessness except on strenuous exercise") and grade 5 the most severe disability ("too breathless to leave the house or breathless when dressing or undressing"). The MRC breathlessness scale is self-completed and takes about one minute to administer. The MRC has been validated for use in patients with COPD (Bestall et al. 1999). The guidelines for PR recommend that respiratory patients with an MRC score of 2-5 should be referred to PR (Bolton et al. 2013).

2.2.2.2 Exercise Capacity

The incremental shuttle walk test (ISWT) was used to measure exercise capacity in this study (Appendix 2, LIVELY CRF, page 9, on CD-ROM). The ISWT is a popular test of exercise capacity for people with COPD and is increasingly being used in research because it is externally paced (Palange et al. 2000). This test was conducted at each time point. The ISWT was conducted in line with standard procedures for conducting the ISWT (Holland et al. 2015). At baseline participants performed two ISWTs to ensure that any change occurring post intervention/follow up was not due to a learning effect (Holland et al. 2014). Two assessors were required to be present for this test; this was usually a combination of a physiotherapist, nurse or a research assistant. Singh et al. 1994 demonstrated the ISWT to be a valid test of exercise capacity in patients with chronic airflow limitation. The ISWT is a recommended test for determining exercise capacity for PR (Bolton et al. 2013). The ISWT ranges from 0-1020m and a higher score indicates a higher exercise capacity.

2.2.2.3 Physical Activity measures

PA was measured at three time points; baseline, post intervention and at follow up using three different measures. Two objective measures and one subjective measure were used to measure PA. An accelerometer (ActiGraph GT3X+) and a sealed pedometer (Yamax DigiWalker CW-700) were the objective measures employed. These devices were worn on the same elastic belt (activity monitor belt) and were worn over seven days. The International Physical Activity Questionnaire (IPAQ) was the subjective measure of PA used in the LIVELY COPD project. Details on how to prepare the ActiGraph and pedometer as well as instructions for how to explain these devices to the participant are included in Appendix 1, (LIVELY CRF instructions, page 8-11 and 18-20, on CD ROM).

2.2.2.3.1 ActiGraph GT3X+

The ActiGraph GT3X+ is tri-axial accelerometer (19 grams; 4.6 cm x 3.3cm x 1.5 cm) which is worn around the waist. The total cost for one ActiGraph GT3X+ (£153.78), one "large" elastic belt (£9.26), one ActiGraph USB cable (£4.94) and one single ActiLife 6 software license (£923.31) was £1091.29 (prices as of January 2014). The ActiGraph measures the time spent in PA at different intensities, step counts and sedentary behaviour. The ActiGraph is factory calibrated so did not require any manual calibration by the research team. Before giving the ActiGraph to participants, the device was fully charged and initialised using the Actilife software (version 6.8.0) and set to record for that participant. The ActiGraph was set to record at 1 second epochs but reintegrated to 15 second epochs for analysis (Byron and Rowe 2016). The ActiGraph was worn around the waist on an elastic belt and positioned on the dominant hip, in line with the anterior superior iliac spine. The elastic belt was fitted onto the participant by the researcher to give a visual demonstration on correct positioning. The ActiGraph was only worn during waking hours. Participants were given both written and verbal instruction on where and when to wear the ActiGraph. The written instruction booklet also contained a diary for participants to record the daily wear time of the ActiGraph (Appendix 3, Activity monitor instruction booklet).

After the seven day wear time, the ActiGraph was returned to the research team by the patient and the data was downloaded using the ActiLife (Version 6.11.9). The number of valid days of wear time were confirmed using the "Wear-time validation" tab. Choi et al. (2011) wear time validation algorithm was applied. Choi et al. (2011) checked for non-wear time using two windows (window 1 and window 2); Non-wear time is calculated using consecutive zero counts >/ 90 minutes (window 1), if non zero counts lasting up to 2 minutes were detected during both 30-minute periods of upstream and downstream checking (window 2) from a specific time interval. All data including >/5 days with >/10 hours of daily wear-time were then scored in ActiLife and exported to Microsoft Excel for data analysis. Each participant's daily levels of; light-lifestyle activity (101-1951 counts per minute (cpm)); total moderate-vigorous physical activity (MVPA) (>/1952 cpm); MVPA accumulated in 10 minute bouts; number of bouts of MVPA accumulated in 10 minutes; sedentary time (<100 cpm); and step counts were calculated

using the Freedson Combination 1998 formula (manufacturer's algorithm). Data was cleaned in Microsoft Excel; ensuring that all days met the wear time criteria and removing any data that was not required for analysis for example Epoch or average step counts.

There is some level of debate regarding the amount of wear time required for a PA data set to be considered valid; there is a variety of hours and days reported in the literature, however there are also a number of studies that do not report this wear time (Byron and Rowe 2016). A minimum of 10 hours of wear time is the most commonly reported wear time in the COPD population and a minimum of 5 valid days across the 7 day period is recommended for a data set to be valid (Byron and Rowe 2016). However given the ambiguity and lack of gold standard guidelines for the number of hours and days for a data set to be valid we explored our data to determine what combination of hours and days would optimise our data (Appendix 4, Data checking and wear time combinations for ActiGraph), yet maintain best practice. Based on the findings, our exploration and guidance from the literature, only data including 5 valid days of ten hours wear time per day were included for analysis. ActiGraph data was checked by OO'S and JW. This was done systematically throughout the downloading and scoring process (Appendix 4, Data checking and wear time combinations for ActiGraph and pedometer pre analysis).

The ActiGraph GT3X+ is a valid instrument to measure PA in people with COPD (Rabinovich et al. 2013). Furthermore Byron and Rowe (2016) conducted a review to understand how activity monitors have been used in COPD research to date. They recommend the use of a tri-axial accelerometer which provides access to raw data; the ActiGraph GT3X+ meets these criteria.

2.2.2.3.2 Yamax DigiWalker CW-700 pedometer

The DigiWalker CW-700 is a pedometer (21 grams; 5cm x 3.8cm x 2.1cm) worn on the waist. The total cost for one DigiWalker CW-700 pedometer was £19.95 (price as of January 2014). The DigiWalker pedometer measures step counts and walking time. The pedometer is factory calibrated so did not require any manual calibration by the researcher. Before the pedometers were distributed, the time on the pedometer was checked and adjusted if necessary. The pedometer was worn alongside the ActiGraph on the belt; the pedometer was worn medially to the ActiGraph. A 20-step test was conducted to confirm the pedometer was working and positioned correctly. The 20-step test needed

to record between 19-21 steps before the pedometer could be sealed with tape. The pedometer was sealed with tape so that participants' could not view their step counts and therefore their PA could not be influenced over the seven day wear time period. The pedometer was fitted onto participants to give a visual demonstration on correct positioning. The pedometer was only worn during waking hours. Participants were also given written information on where and when to wear the pedometer. The written instruction also contained a diary for participants to record their daily wear time of the pedometer (Appendix 3, Activity monitor instructions booklet).

After the monitoring period (at baseline, post intervention and follow up), data recorded on the pedometer on daily step counts were manually recorded into the participant's CRF. A valid day of pedometer data required steps to be recorded between 100 and 50,000 steps (Matthiesson et al. 2015). After removal of invalid days, datasets with >/5 valid days were analysed, data was checked systematically with JW (Appendix 4, Data checking and wear time combinations for ActiGraph and pedometer pre analysis).

The Yamax DigiWalker pedometer is accurate and reliable for counting steps (Crouter et al. 2003, Schneider et al. 2004). The Yamax DigiWalker pedometer has previously been used to measure PA in the COPD population (Hospes et. al 2009, Tabak et al.2014)

2.2.2.3.3 International Physical Activity Questionnaire

PA was assessed subjectively with the IPAQ long form at each time point (Appendix 2, LIVELY CRF, page 19-23, on CD-ROM) The IPAQ contained 25 questions which include four different PA domains: work outside the home (7 questions), transport (6 questions), work inside the home (6 questions) and leisure time (6 questions). The IPAQ's scoring protocol (Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ) – Short and Long Forms November 2005) was used to summarise the results**.** The data from these questions can then be used to calculate an individual's total MET-minutes spent in walking, moderate and vigorous PA. There are two questions on sitting time; one question on average sitting time on a week day and one question on average sitting time on a weekend day. The IPAQ is self-completed and takes about 15 minutes to administer. The IPAQ is a validated measure of metabolic equivalent minutes (MET-minutes) spent in different physical activities and sedentary behaviour (sitting time) over the previous seven days (Craig et al. 2003). The

IPAQ has been validated for use in healthy individuals (Craig et al. 2003) and previously used to measure PA in the COPD population (Liao et al. 2014).

2.2.2.4 HRQoL questionnaires

2.2.2.4.1 EQ-5D-5L Health Questionnaire

The EQ-5D-5L, English version for the UK (Appendix 2, LIVELY CRF, page 24-26, on CD-ROM) was used in the LIVELY COPD project to measure health status. The EQ-5D-5L was completed at all-time points, it is self-completed and takes about three minutes to administer. The EQ-5D-5L consists of two parts; the descriptive system and the visual analogue scale (VAS) (0-100) rating of health. The descriptive system contains five dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression which are rated on 5-point Likert scale. Higher scores on these five questions indicate increased problems in these five dimensions. Response patterns for the numbered values of the five questions are reported from optimal health status (11111) to severe problems in all dimensions (55555). Using the response patterns an index value is calculated using the EQ-5D-5L Index Value Calculator Version 1. A lower score indicates a worse perceived health status. A separate score is recorded from the VAS scale, with a lower number indicating worse perceived health. Nolan et al. (2016) found the EQ-5D-5L to be valid and responsive measure of health status in people with COPD. The EQ5D5L has previously been used in the COPD population (Gillespie et al. 2013, Briggs et al. 2010, Cross et al. 2010.

2.2.2.4.2 COPD Assessment Test (CAT)

The CAT aims to quantify the impact of COPD on the patients' health or health related quality of life (Appendix 2, LIVELY CRF, page 27, on CD-ROM). This is a self-administered outcome measure and takes about three minutes to administer. The CAT was completed at all-time points in the LIVELY COPD project. It consists of eight questions which are scored on 6-point Likert scale. The eight questions relate to common symptoms of COPD and quality of life including cough, phlegm, chest tightness, dyspnoea, usual activities, and confidence in leaving their home, sleep and energy levels. A higher score on the Likert scale indicates reduced symptoms or impact on quality of life. For example in relation to cough a "0" indicates "I never cough" and "5" indicates "I cough all the time". The scores for each question are then added up to give a total

score between 0-40. A higher score indicates a more severe impact of COPD on the patient's life. The CAT can be expressed as an absolute value or the values can be categorised according to the level of impact of COPD on the patients' health: >30 very high, >20 high, 10-20 medium and <10 indicates a low impact. The CAT was developed specifically for the COPD population and is validated in this population (Jones et al. 2009).

2.2.2.5 Transtheoretical model (TTM)

The TTM has previously been used to assess individuals' health behaviours including PA (Hutchinson et al. 2009). The TTM comprises of stages of change (SOC), self-efficacy and decisional balance.

2.2.2.5.1 Stages of change Questionnaire (SOC)

The SOC Questionnaire (Appendix 2, LIVELY CRF, page 28, on CD-ROM) is used to identify what stage of change an individual is at in relation to their PA behaviour (Marshall and Biddle 2001). The stages within this questionnaire range from pre-contemplation (not thinking about taking part in PA over the past 6 months) to maintenance (taking part in regular PA activity over the past 6 months), including five different stages. PA was defined in this questionnaire and examples of what regular PA were given to allow participants to make an informed decision of which stage best reflected their current status. The questionnaire is adapted from Stages of Exercise Behaviour Change Questionnaire by Marcus et al. (1992a). This questionnaire is self-completed and takes about three minutes to administer; it consists of five statements and the participant chooses the one which best describes their current stage. This questionnaire has previously been applied to the people with bronchiectasis (Wilson et al. 2016, Bradley et al. 2015). This questionnaire has been validated in healthy populations (Cardinal 1997).

2.2.2.5.2 Marcus's Self Efficacy

Marcus's Self Efficacy Questionnaire (Appendix 2, LIVELY CRF, page 29, on CD-ROM) provides information on participants' confidence to be physically active in certain situations (Marcus and Forsyth 2009). Self-efficacy has been identified as one of the clearest correlates of PA in adults (Bauman et al. 2002). This questionnaire is self-

completed and takes about three minutes to administer; it was administered at each time point. It contains five questions and an additional disease specific question ("When I have respiratory symptoms") was included, this question has been included in previous work by the research team in bronchiectasis (Bradley et al 2015). The items are based on 5-point Likert scale with a higher score indicating a greater self-efficacy to engage in PA. This questionnaire has been used in patients with bronchiectasis (Wilson et al. 2016, Bradley et al. 2015). This questionnaire has been validated in healthy individuals (Marcus et al. 1992a).

2.2.2.5.3 Decisional balance

The decisional balance was conducted at baseline only (Appendix 2, LIVELY CRF, page 29-30, on CD-ROM). Participants were asked, "In your opinion what are the benefits of taking part in physical activity?" and, "In your opinion what are the downsides of taking part in physical activity?" These questions were adapted from Marcus and Forsyth (2009). These anticipated barriers and benefits were then used by the provider of the intervention to shape the PAI.

2.2.2.6 Global Rating of Change (GROC)

The GROC scale in the current study was adopted from Perry (2007). This scale is used to assess if a patient has improved, deteriorated or experienced no change over a period of time, usually with respect to an intervention (Appendix 2, LIVELY CRF, page 48, on CD-ROM). This instrument is self-completed and takes two minutes to administer. In LIVELY, COPD project participants were asked to recall their ability to be physically active at baseline compared to either post intervention or follow up; in terms of "better," "worse," or "no change". If there had been a change participants were asked to rate the magnitude of this change across a seven point scale from "a tiny bit-almost the same," along the spectrum to "a very great deal." Participants were then asked to rate the importance of this change or lack of change to them across the same seven point scale. The GROC scale has been previously used in COPD research as an anchor method to calculate the minimal clinically important difference (MCID) for the ISWT (Singh et al. 2008) and the responsiveness of the CAT (Dodd et al. 2010).

2.2.2.7 VAS for achieving outcome goal

Participants in both PR and the PAI were to set an outcome goal; something functional they would like to achieve by the end of their respective programme, for example being able to walk to the local post office. This instrument is self-completed and takes two minutes to administer (Appendix 2, LIVELY CRF, page 50, on CD ROM). Post-intervention; all participants were asked to rate on a 10-point VAS whether they had achieved this goal: 0 representing "not met at all" and 10 indicating that the goal was "fully met."

2.2.3 Qualitative Assessment

Semi-structured interviews were conducted post-intervention to explore participants' experience views of the programme. Full details of the qualitative component are reported in the Chapter 4.

2.3.4 Development of the LIVELY COPD project clinical research form (CRF)

A CRF was developed to record all baseline demographics and outcome measure data at each point (Appendix 2, LIVELY CRF, on CD-ROM). A CRF instruction manual was also developed with all relevant information on how to conduct each study visit and outcome measure in a standardised manner (Appendix 1, LIVELY CRF instructions, on CD-ROM). It also contained a task log indicating the primary person responsible for each task. The instruction manual contained information on how to plan for study visits, administer outcome measures in standardised fashion and details on how to initialise position and download data from the activity monitors. All versions of the CRF and associated instruction manual were developed in accordance with the LIVELY study protocol; feedback was provided on all draft versions by members of the LIVELY COPD project team. Pilot testing sessions with the research team were conducted to ensure the order of the outcome measures and clarity of instructions. The LIVELY COPD project was conducted in both the BHSCT and the WHSCT; separate site specific versions of the CRF and instruction manuals were created for each trust to contain the correct phone numbers for emergencies and contact details for the staff in each trust and to enable use of each specific trust logo.

2.3 The Physical Activity Intervention

2.3.1 Training of providers

Three healthcare professionals (HCPs) (2 physiotherapists and 1 respiratory nurse) were trained to deliver this intervention. These three individuals were recruited from within the NICRN. The intervention providers attended five training sessions in total, two were conducted prior to the recruitment of the first patients to the LIVELY COPD project and three throughout the course of the intervention (Appendix 5, PAI file, section 9, Training, on CD-ROM). The intervention providers were mentored throughout the delivery of the intervention by two experienced members of the research team (JB and SMcD). The mentors had contact with the providers before and after the delivery of each consultation in the intervention to each participant. The providers were also given materials for delivering the intervention (Appendix 5, PAI file, section 1-7, on CD-ROM).

2.3.2 The physical activity intervention

Participants recruited to the LIVELY study were either randomised to PR or to the PAI, following their baseline outcome measure assessment. The PAI was a clinician facilitated pedometer driven, 12 week walking intervention. The pedometers were unsealed for the intervention to allow them to be checked by participants therefore be used as a motivational tool. The PAI considered the, 'capability', 'opportunity', 'motivation' and 'behaviour,' (COM-B) model of behaviour change and included 20 behaviour change strategies (BCS) (Appendix 6, List of Behaviour Change Strategies for the LIVELY PAI (amended)) (Michie et al. 2014, Michie et al. 2013). The current guidelines for PA and influences from the stages of changes were also considered in the development of the intervention (BASES 2011, Marcus and Forsyth 2009). Participants had seven face to face consultations (consultation 1-6 and consultation 12) with an intervention provider; five consultations were conducted over the phone (consultations 7-11). Face to face consultations were expected to last up to one hour and were conducted in an outpatient hospital department and telephone consultations were expected to last about 15-20 minutes. However there was some flexibility permitted, participants could transition to telephone contact earlier if they felt they were ready. The first week (familiarisation week), the participants were given their unsealed pedometer (Yamax Digiwalker CW700) and step diary. The intervention provider demonstrated how to access the seven day recall

on the pedometer and the correct position of the pedometer. Participants also completed a 20 step test to ensure the pedometer was correctly recording step counts. Participants then used this first week; the "familiarisation week," to become familiar with using the pedometer and documenting their steps in the diary.

When participants returned the following week (week 2), an outcome goal relating to an activity or function was set, for example "To be able to walk to the centre of town on my own without fear." This was revisted during the intervention, and reviewed at the end to determine if it had been achieved. At week 2 the intervention provider also reviewed the step diary and the pedometer from the familiarisation week to ensure they matched. A ten minute self-efficacy walk was also conducted to determine how many steps the participant could achieve in ten minutes. The result of this ten minute self-efficacy walk and the participants' baseline daily step count was used to set a goal for the subsequent week (Table 2.3 Examples of how weekly step goal was set). Participants also set an action and coping plan each week to set out how they planned to achieve their goal and how they would overcome any unexpected situations or anticipated barriers. The providers explored with the participants any prompts or reminders to do walking. This goal setting and action and coping planning were conducted each week, from week 2-11. Additional strategies could be employed by the provider to encourage the participant to be more physically active based on the participants' stage of change, (Appendix 5, PAI file, section 7, Toolkit, on CD-ROM). Participants also received disease specific education at consultations 1 and 5: management of breathlessness and positions of ease (consultation 1) and inhaler technique (consultation 5). At the final consultation (12), the intervention provider revisited the barriers encountered by that participant and the successful strategies used to overcome these. They also explored the benefits the participant experienced from the programme and discussed plans for maintenance as well as relapse prevention. The protocol facilitated the intervention to be extended by one week if the provider felt that the participant needed an additional week (13 week intervention) for example if the participant had missed an appointment during the intervention.

Intervention materials (LIVELY manual, pedometer, Living Well with COPD (LWWCOPD) Booklet)

All participants in the LIVELY PAI were given a pedometer, a LIVELY manual and a LWWCOPD booklet. The LIVELY manual contained an action and coping plan for each week where they documented their step goal. It also contained a step diary for participants to record their daily step count. This manual was developed specifically for the LIVELY intervention by members of the research team and is included in the appendices (Appendix 7, LIVELY PAI Patient Manual, on CD-ROM). The LWWCOPD booklet is an educational booklet specifically developed for people with COPD which was designed to be used in PR (Cosgrove et al. 2013).

2.3. 3 Pulmonary rehabilitation

PR was delivered by clinicians as per usual practice. Ten PR sites across two trusts were included in the LIVELY COPD project. The key staff delivering the PR programme included respiratory physiotherapists and nurses with experience in management of COPD and in delivering PR. The PR programmes consisted of a 6-week supervised group based face to face outpatient (community or hospital location) programme and was delivered according to well established guidelines (Bolton et al. 2013). The exercise component usually lasted for one hour and was delivered twice weekly. It generally consisted of cardiovascular exercises and upper and lower body strengthening exercises. A diary was used during PR to record the exercises undertaken and the level of breathlessness measured on the BORG scale was also noted by each participant. Education sessions (30-60 minutes) were delivered at least once weekly. Patients were provided with a booklet of exercises and encouraged to perform these independently on a third occasion. Patients in the PR groups also received the LWWCOPD booklet (Cosgrove et al. 2013).

2.4 Conclusion

This chapter describes the procedures for data collection in the LIVELY COPD project (Chapter 3), including the collection of anthropometric and demographic data and outcome measures at all-time points. The PAI and PR have also been described.

Tables

Table 2-2 Summary table of outcome measures

Outcome measure	**Purpose**
Medical Research Council Breathlessness Scale	Breathlessness
Incremental Shuttle Walk Test	Exercise capacity
ActiGraph GT3x	Physical Activity (objective)
Pedometer	Physical Activity (objective)
International Physical Activity Questionnaire	Physical Activity (subjective)
EQ-5D-5L	Health related quality of life
COPD Assessment Test	Health related quality of life
Stages of change questionnaire	Transtheoretical model
Marcus self-efficacy	Transtheoretical model
Decisional balance	Transtheoretical model
Global rating of change	Subjectively assess degree of change/ lack of change
Visual analogue scale	Subjectively assess degree of achievement of participants' functional goal

Table 2-3 Examples of how weekly step goal was set

Total weekly step count for 7days from previous week	19,747
Average daily steps from previous week	2,821
Self-efficacy walk result	1,027
Agreed step goal	4,300 on 7/7 days
Example 2	
Total weekly step count for 7days from previous week	39,935
Average daily steps from previous week	5,705
Self-efficacy walk result	992
Agreed step goal	8,000 on 5/7 days
The step target for each subsequent week was individually tailored agreed between the physiotherapist/nurse and the participant by referring to 1) current walking behaviour identified from the mean daily step count for the previous week calculated from the pedometer steps/walking diary, and 2) the number of steps accumulated during the 10-minute 'self-efficacy walk'. The consultations included discussion of current physical activity behaviour, the identification of barriers and facilitators to change, strategies to enable patients to meet walking goals and address barriers, and strategies to enhance confidence/self-efficacy around achieving goals (self-efficacy, goal setting), action and coping plans, problem solving, social support, information on the consequences of behaviour from credible sources, and maintenance and preventing relapse.	

Chapter 3 - Clinician facilitated physical activity intervention versus pulmonary rehabilitation in improving physical activity in COPD: A feasibility study

3.0 Chapter overview

The LIVELY COPD project was a randomised controlled feasibility study which aimed explore to the effectiveness of a PAI (clinician facilitated pedometer driven walking intervention) versus PR in improving PA in COPD. This chapter will summarise the methods used in this trial, the results of the assessment of feasibility of the LIVELY COPD project according to the NIHR criteria for feasibility, the results of the assessment of feasibility of the LIVELY PAI and discuss the results. The role of each the members on the study is summarised in Table 3.1.

Table 3-1 Role of members on the study team

Personnel	Role
Orlagh O'Shea	-Conducting and scheduling outcome measures assessments -Data management -Analysis of results -Write up of methods
Dr Brenda O'Neill	-Development of LIVELY PAI - Selection of outcome measures -Development of clinical research records -Conducting outcome measure assessment (back up for annual leave) -Analysis of results -Intellectual contribution to and write up of chapter
Prof. Judy Bradley	-Development of LIVELY PAI - Selection of outcome measures -Development of clinical research records -Analysis of results -Intellectual contribution to and write up of chapter
Prof. Suzanne McDonough	-Development of LIVELY PAI -Selection of outcome measures -Development of clinical research records -Analysis of results -Intellectual contribution to and write up of chapter
Dr Adele Boyd	-Conducting outcome measures assessment
Dr Denise Cosgrove	-Screening of patients for the LIVELY COPD project -Delivery of the LIVELY PAI
Dr Catherine Hanratty	-Screening of patients for the LIVELY COPD project

	-Delivery of the LIVELY PAI
Adrian McDonald	-Screening of patients for the LIVELY COPD project -Delivery of the LIVELY PAI
Dr Terence McManus	-PI for the WHSCT
Dr Lorcan McGarvey	-PI for the BHSCT
Prof. Madelynne Arden	-Development of the LIVELY PAI
Prof. Thierry Troosters	-Development of the LIVELY PAI
Dr Tim McDonnell	-Development of the LIVELY PAI

3.1 Introduction

Globally, PR is established as a core component in the management of COPD and has been shown to enhance health related quality of life, reduce dyspnoea and improve exercise capacity (McCarthy et al. 2015). The majority of PR programmes are supervised outpatient-based, and delivered in a group format (Bolton et al. 2013). Dropouts and non-adherence rates from PR are high, emphasising that PR may not suit all patients with COPD (Jones et al. 2014 Steiner et al 2016). The current availability of PR programmes is unable to reach all those with COPD who would potentially benefit from PR (Steiner et al 2016, Rochester et al. 2015). Furthermore while Spruit et al. (2013) report that the components of PR which are aimed at increasing exercise tolerance and improving self-efficacy could be considered a good platform to improve daily PA levesl, there is limited evidence to indicate whether the improved exercise capacity following PR translates into improved PA levels in COPD (Troosters et al. 2010b, Watz et al. 2014). There is therefore a need to explore alternative platforms to delivering exercise/PA training traditionally delivered in the context of PR.

PA is fundamental for the prevention of chronic disease and premature mortality (Min-Lee and Skerritt 2001). Walking represents a form of PA that has been shown to be effective in increasing PA in clinical populations and is necessary for activities of daily living (McDonough et al. 2013). Although studies in COPD have demonstrated the effectiveness of individualised walking programmes, these alternative programmes do not seem to be offered within current models of healthcare provision for COPD (Wilson et al. 2014). A home-based pedometer-driven walking intervention may offer an innovative and alternative method of delivering PA training that could be provided to

large numbers of patients with COPD on an individual basis. Walking could provide for flexibility around life commitments and promote a change in activity levels.

The importance of conducting a feasibility study prior to a full RCT has been emphasised by key funders such as the MRC and the NIHR, as well as recent publications (NIHR 2012, Craig et al. 2006, Thabane et al. 2010, Lancaster 2015).

3.1.1 Aim

The aim of this study was to assess the feasibility of conducting a trial to investigate the effectiveness of a clinician facilitated PAI (PA consultation and a pedometer-based walking programme) versus PR in improving PA in COPD patients referred to PR.

3.1.2 Objectives

I. To use the NIHR criteria (Table 3.2) to assess the feasibility of conducting a trial to compare the effectiveness of PAI versus PR in patients with COPD referred to PR.

II. To assess the feasibility of delivering a PAI to patients with COPD

3.2 Methods

The reporting of this trial adheres to the Template for Intervention Description and Replication (TIDieR) (Hoffman et al. 2014), (Appendix 8, TIDieR checklist results for the clinician facilitated physical activity intervention versus pulmonary rehabilitation in improving physical activity in COPD: A feasibility study). See Chapter 2 for full details on the LIVELY PAI, the procedures followed for the outcome measure assessment, data collection and the study materials for the LIVELY COPD project.

3.2.1 Design

The study design was a multicentre mixed methods randomised, parallel-group, feasibility study. The full study protocol for LIVELY is available at https://clinicaltrials.gov/. Ethical approval was obtained from the NI Research Ethics Committee 13/NI/0014 and site governance approval was obtained from the BHSCT and

the WHSCT (Appendix 9 Ethical approval from the Northern Ireland research ethics committee, Appendix 10 Study approval from the BHSCT governance, Appendix 11 Study approval from the WHSCT governance).

3.2.2 Population

Patients with COPD (n=50) referred for PR to any of the ten sites that provide PR within the BHSCT and the WHST were included. All PR sites reported that they were adhering to the BTS guidelines for PR prior to the commencement of and midway through the study (Bolton et al. 2013). Patients with a primary diagnosis of COPD (NICE 2010), a good understanding of written English (as reported by the individual patient) and in a stable phase (no change in symptoms or medication in previous 4 weeks) at the time of assessment were included. Exclusion criteria were inability to safely take part in a walking programme or PR (e.g. unstable angina, neurological, spinal or skeletal dysfunction affecting ability to exercise) as decided by the PR team or inability to comprehend or follow instructions (e.g. dementia), (Appendix 1, LIVELY CRF instructions, The screening and recruitment process page 5-6, on CD-ROM).

3.2.3 Recruitment and randomisation

Patients were randomly assigned to two groups using computer-generated block random numbers by a member of the team not involved in any other aspect of the study in order to ensure allocation concealment: Group 1-PAI or Group 2- PR. The allocation was retained in sealed opaque envelopes which were opened to reveal group allocation only after consent and after completion of baseline assessment. Patients were stratified according to HSC Trust to help ensure that equal numbers of patients within each Trust were randomised to each group.

As this was a feasibility study, no formal sample size calculation was used. Based on previous publications a sample size of 50 was deemed appropriate to achieve the aims/objectives of this study (Sim and Lewis, 2012). This sample size also reflected a realistic target for the intervention period and one which was anticipated would provide sufficient information on the feasibility to inform future studies.

3.2.4 Interventions:

Participants were randomised to either the PAI or PR.

The PAI intervention was a 12 week clinician facilitated pedometer driven walking programme. All participants were provided with a Yamax Digiwalker CW700 and manual with weekly step diary and action and coping plans. Participants had weekly contact with the interventionist (specifically trained physiotherapist or nurse). Each week participants set a step goal based on their previous weeks step count and their self efficacy walk. (Full details of the intervention can be found in Chapter 2).

Participants in the PR group attended the supervised exercise class twice a week for 6 weeks and were also given a booklet with exercises to perform independently on a third occasion. (Full details of PR can be found in Chapter 2)

3.2.5 Data collection

All screening, recruitment, adherence (number of sessions attended) and drop outs as well as the occurrence of adverse events were recorded. Demographics (gender, age, height, and weight), medical and social details and spirometry results were obtained at baseline assessment. Patients attended four study visits for outcome assessment: baseline assessment was conducted over two appointments, 7 days apart (Visit 1 and 2). Participants were assessed again post-intervention (Visit 3) and at 3 months following the end of the intervention (Visit 4). All data was collected by a trained independent assessor, either a physiotherapist and/or a research assistant, not involved in the delivery of intervention.

The following outcome measures were collected: PA with the ActiGraph GT3X+ accelerometer (Rabinovich et al. 2013) and a sealed Yamax Digiwalker CW700 (Schneider et al. 2004) pedometer which were worn around the waist for seven days during all waking hours, as well as the long form of the IPAQ (Craig et al. 2003); exercise capacity with the ISWT (Singh et al. 1994); health status with the CAT (Jones et al. 2009) and EQ5D5L (Briggs et al. 2010); and a modified GROC scale (Perry 2007). Participant stage of change was also assessed and decisional balance was assessed at baseline only

(Marcus and Forsyth 2009). Full details on data collection methods can be found in Chapter 2.

3.2.6 Feasibility of the PAI

Each week participants set a step goal. The step goal and the actual step count achieved by the participant were recorded and analysed to assess whether participants were reaching their goal each week, and the degree of improvement. Additionally, an outcome goal was set at baseline, and at the post intervention assessment (visit 3) participants were asked to report the extent to which they met this goal on a visual analogue scale (0-10) with ten being "fully met". The PAI was considered to be feasible based on whether individuals' could achieve their weekly step goal, achieve their overall outcome goal, and increase their step count across the intervention.

3.2.7 Data analysis

All participant screening and outcome measure data was entered into SPSS version 22.0 (SPSS Inc., Chicago, IL). Data entry was independently assessed for accuracy and analysed per protocol. All continuous variables were checked for normal distribution using the Shapiro-Wilk Test, which confirmed that most of the data were normally distributed; BMI, FEV1% and FVC were not normally distributed. Descriptive statistics were used to summarise the screening, recruitment, adherence and population demographics. Only ActiGraph data that contained a minimum of five days of ten hours wear time were used for analysis; and only sealed pedometer data that had a minimum of five days of 100-50,000 steps were used for analysis (Byron and Rowe 2016, Matthiessen et al. 2015). As this was a feasibility study, we were not focused on statistical significance and therefore mean difference (standard deviation (SD)), with 95% confidence interval (CI) was estimated at each follow-up time point for all outcome measures using paired t tests. Data is presented mean ([95% CI] or (SD)), and nominal data is presented as percentages.

All pedometer data relating to weekly step goals and steps achieved were recorded in Microsoft Excel 2010. Mean weekly step goals and mean weekly steps achieved were calculated and plotted graphically to demonstrate how these numbers tracked each other over time during the PAI. The mean difference between participants first and last recorded

mean daily pedometer step count was also calculated. Finally participants VAS scores for whether they felt they had achieved their outcome goal were also recorded and a mean score calculated.

3.3 Results

3.3.1 Participants

Participant flow through the study is summarised in Figure 3.1. Six hundred and fifty one participants were screened between 4th April 2014 and 27th July 2015. Of those eligible 11% (n=50) were recruited (see Table 3.3 for full screening data). Patients with a mean (SD) age of 64.1(8.6), 24M and FEV_1 1.4 (0.6) L/min were recruited over the 16 month period. Patients were assessed and randomised to PAI (n=24) or PR (n=26) One participant who was randomised to the PAI attended PR instead; PR (n=27) and PAI (n=23).

Patient characteristics are available in Table 3.4. This group had complex needs; n=30 had more than 2 self-reported comorbidities and were prescribed multiple medications (mean 7.82 (3.84) which includes their specific respiratory medications). Additional patient characteristics are available in the Appendices, Appendix 12.

3.3.2 Intervention adherence

There were 26% (6/23) drop outs in the PAI group. Reasons for not starting and drop outs are detailed in Figure 3.1. The PAI was adhered to (attended at least 75% sessions) by all 17/17 (100%) of those who did not drop out (Williams et al. 2011). The time taken to compete the intervention was 12.4 weeks, ranging from 10.7 to 16.3 weeks and participants on average completed a mean 11.8 (0.6) of the 12 planned consultations.

There were 52% (14/27) drop outs in the PR group. Reasons for not starting and drop outs are detailed in Figure 3.1. PR was adhered to (attended at least 75% sessions) by 9/13 (70%) of those who did not drop out (Williams et al. 2011). Participants who adhered to PR attended a mean of 10.5 (1.2) of the 12 planned classes.

Figure 3.1 also details the retention rates for participants providing post intervention (visit 3) and follow-up (visit 4) outcome measures: post intervention n=18 (PAI) and n=19 (PR) and at follow up n= 15 (PAI) and n= 18 (PR). These numbers relate to participants providing at least one outcome measure. Some participants did not adhere to their intervention but returned for outcome measure assessment.

3.3.3 Outcome measures

A range of outcome measures were included in this study. The mean (SD) time taken in minutes to administer the study outcome measures at baseline was visit 1 80.2(20.0), and 46.9(21.1) at visit 2; the average time taken to administer the study outcome measures at post intervention was 62.9(12.6) and at 3 month follow-up was 49.6(15.6).

The available outcome measure data for the ActiGraph and pedometer were generally less than the paper based and ISWT outcome measures as we used the recommended wear time criteria on this data; only data with five days of ten hours of wear time was included (Byron and Rowe 2016) and only pedometer data with five valid days of between 100-50,000 steps were included for analysis (Matthiessen et al. 2015). A few patients who could not attend follow up appointments completed the outcome measures by post. Specific details and reasons for all missing data are included in Table 3.5.

3.3.3.1 Post intervention (visit 3)

The mean (SD) daily step count as recorded by the ActiGraph for the PAI group at baseline was 3305.6 (1960.2) steps for n=17 participants, and at post intervention was 4768.2 (2992.2) steps for n=14 participants; the mean difference (SD) [CI] was 972.0 (3230.3) [-1080.3 to 3024.4], n=12. The mean (SD) daily step count as recorded by the ActiGraph for the PR group at baseline was 3946.3 (2263.1) steps for n=27 participants and at post intervention was 3476.6 (2307.9) steps for n=12 participants; the mean difference (SD) [CI] was 4.3 (662.7) [-440.9 to 449.5], n=11.

Moderate-vigorous PA measured by the ActiGraph increased for the PAI group and decreased for the PR group. Post intervention the pedometer step count (sealed pedometer) increased in both groups, the increase observed in the PAI group was in line with the MCID (Demeyer et al. 2016). PA levels assessed by the IPAQ demonstrated

improvements in both groups from baseline to post intervention. The ISWT scores improved for both groups. The CAT score improved for both groups from baseline to post intervention. The EQ5D5L index score was unchanged for the PAI group and there was an improvement of 0.1 in the PR group from baseline to post intervention. There were improvements in both groups in the EQ5D5L VAS scores post intervention. Table 3.6 details the mean difference (SD) [CI] for ActiGraph, pedometer and IPAQ data from baseline to post intervention. Table 3.7 details the mean difference (SD) [CI] for ISWT, CAT and EQ5D5L data from baseline to post intervention.

3.3.3.2 Minimal clinical important difference

For those who adhered to the PAI (n=17); ActiGraph step counts were available for n=11 at baseline and post intervention, 36% (n=4) met the MCID for step count (change of 600-1100 (Demeyer et al. 2016), CAT scores were available for n=16 at baseline and post intervention, 37.5% (n=6) of these met the MCID (change of 2 (Kon et al. 2014)). ISWT scores were available for n=15 at baseline and post intervention, 33.3% (n=5) of these met the MCID (change of 47.5m (Singh et al. 2008)).

For those who adhered to the PR (n=9); ActiGraph step counts were available for n=5 at baseline and post intervention; none of these met the MCID for step count (Demeyer et al. 2016). ISWT scores were available for n=5 at baseline and post intervention, 20% (n=1) of these met the MCID (Singh et al. 2008) and 44.9% (n=4/9) met the MCID for CAT (Kon et al. 2014).

3.3.3.3 Follow-up (visit 4)

Figure 3.2 represents the mean daily ActiGraph step counts at baseline (visit 1 and 2), post intervention (visit 3), and at follow-up (visit 4) for both groups. There appears to be a general trend towards increasing step counts across the three time points in the PAI group, and in the PR group there was a decline in step count from baseline to post intervention, and then an increase at follow up. The mean (SD) and frequency data follow up data for all outcome measures is available in the Appendices (Appendix13).

3.3.4 Adverse events (AEs)

There were 4 related and unexpected AEs (PAI: (n=3) i.e. blister on the right heel and big toe, flare up of a knee swelling, reaction to nickel on pedometer due to a nickel allergy); and PR (n =1) i.e. dizziness when leaving out patient department after an appointment for assessment had been completed. These AEs were managed by providing advice to the patients for resolution, and no-one withdrew based on these AEs.

3.3.5 Feasibility of the PAI

In relation to the achievement of weekly step goal, participants appeared to overachieve their step goals in the first week of the PAI, but as the intervention progressed the step goal and step count achieved aligned more closely (Figure 3.3). For those who provided step counts at two time points, most patients (17/20) demonstrated an increase in their step count following the PAI; step count recorded by the pedometer improved by a mean (SD) 2087(252) steps between week 1 and the last step count recorded (Figure 3.4). Following the PAI, participants rated whether they had met their outcome goal set out at the start of the intervention using the VAS scale (0=not met at all, 10 = fully met). VAS scores were available for n=16/18.; n=1 was unwell and did not travel for outcome measure assessment and n=1 could not remember his goal. Overall participants reported achieving their goal; mean 8.8 (SD) (2.9).

3.4 Discussion

This feasibility study demonstrates key considerations for conducting a future trial of a PAI versus PR in COPD. The applicable NIHR criteria for the success of a feasibility trial were met and based on the results of this study, including the qualitative data, a future trial is feasible. Before proceeding to a larger trial, strategies for reducing dropouts, improving adherence and for optimising efficiency of data collection would need to be considered. The PAI was effective for increasing step count and feasible to deliver.

Recruitment to this study was generally feasible; we planned to recruit over a period of 14 months and achieved target at 16 months. Our recruitment process for this feasibility study was uniquely influenced by opportunities for ease of access to programmes; we

confined the study to two HSC Trusts. Recruitment rates can vary across the COPD literature. For example, recruitment rates of 3.9% (103/2646) in a recent study exploring the feasibility of conventional PR versus a web based PR (Chaplin et al. 2017) and 63.3% 57/90 in a cohort study on PR in COPD (Cosgrove et al. 2013) have been reported. In research on PAIs in COPD, 18.1% (140/775) were recruited in a study exploring the effects of a short-term (3 months) and a long-term (18 months) exercise program on self-reported disability and physical function in COPD (Varga et al. 2007) and 89.8% (71/79) in a study exploring the effects of supervised high intensity continuous or interval training with unsupervised self-paced training (Berry et al. 2003). A large number of patients attending the PR clinics were not suitable for this study for example due to musculoskeletal problems, vascular problems, cardiac issues (198/601, 33%); our criteria helped us to identify these patients and triage their care to an appropriate service, test or procedure prior to further assessment for PR. Not all patients referred for PR were interested in taking part (n=131/601, 22%), and a small number (44/601, 7%) had COPD but this was not the primary respiratory diagnosis and they were therefore excluded. This study provides data to estimate the number of sites that would be needed for a larger trial, the estimated sample size for full scale trial is 150 (75 per group) to allow us to detect a 1500 between group step difference with 80% power, taking into account the current MCID for this population (Demeyer et al. 2016). Broader inclusion criteria to include these patients, as well as more PR sites, could improve the recruitment rates. To achieve this recruitment target for a larger trial we would need to explore the capacity for recruitment at each PR site.

The dropout for the PAI (26%) was lower than the dropout in PR (52%). A number of participants in the current study dropped out of PR for health reasons, patients with COPD can experience frequent exacerbations and often present with a number of comorbidities (Steiner et al. 2016). There were other barriers to participation in the PR group that had the potential to be overcome in the PAI; the individualised and flexible nature as well the opportunity for phone contact could have facilitated participation for participants who did not enjoy the group setting, had transport difficulties or were restricted in their flexibility due to other commitments. The qualitative component further explored barriers to adherence; the results of this are reported in Chapter 4. Furthermore the dropout rate for PR (52%) was higher than that reported (29%) in a recent PR audit conducted in England and Wales (Steiner et al. 2016). Reasons for this higher rate of dropout are unclear, and

previous studies in PR in the Northern Ireland COPD population have reported dropout rates which are more consistent with the rest of the UK (between about 10%- 28%) (Cosgrove et al. 2013, O'Neill et al. 2008). Therefore prior to embarking on a future trial strategies could be explored to reduce drop out rates from PR. For example, dropout rates from PR could possibly be reduced through the implementation of quality assurance measures and audit to ensure PR programmes are fully embedded as guidelines recommend (Steiner et al. 2016). Additionally, identifying the characteristics of patients that are less likely to drop out as well as phenotypes of patients who are at risk of dropping out (for example patients with a lower socioeconomic status) (Steiner et al. 2017) might help reduce dropouts of patients in a future trial and enhance the feasibility.

A high number of participants did not meet the wear time criteria for the ActiGraph (Byron and Rowe 2016). A future trial could consider less stringent wear time rules to optimise data or consider utilising a different monitor. Although the ActiGraph GT3X is considered one of the most valid activity monitors for measuring PA in people with COPD (van Remoortel et al. 2012), a future trial should explore with patients where they are most likely to wear an activity monitor e.g. wrist, thigh, ankle, or waist. Popular activity monitors such as the Fitbit have been validated in people with COPD and could be considered in a future trial to maximise PA data (Voojis et al. 2014). Additionally, some data was lost due to error in researcher download (Table 3-5), a standard operating procedure has been developed to prevent this happening in the future (Appendix 14). Finally step count was also assessed with a pedometer which was sealed (to hide the step count data) at baseline and again post intervention. Current evidence indicates that these two devices are not interchangeable, and the ActiGraph is a more precise measure of PA and so it may be more suitable for data collection as an outcome measure for research (O'Neill et al. 2017a). The pedometer (unsealed) however did appear to be a feasible tool for setting and monitoring step counts during the PAI and it provided good motivation to participants.

The PAI appears to be safe to deliver; with few minor adverse events. Recording the achievement of weekly step goals as an indication of feasibility has been reported in other studies (Paxton et al. 2017). Throughout the intervention the step goals and actual steps achieved were closely matched with most patients achieving their goal each week similar to other studies in clinical populations (McDonough et al. 2013). The greatest

improvement was observed in the first week with smaller, more gradual improvements over time; perhaps just wearing the monitor in the first week provided an initial motivation. The pedometer data obtained from participants during the PAI, demonstrated (for those who recorded step counts at two time points) the mean increase (2087) was almost double that of the upper end of the MCID for step count in the COPD population (600-1100) (Demeyer et al. 2016), demonstrating the potential efficacy of this intervention and potential for use in a future trial. Patient selection for such interventions may be important. A recent multicentre randomised controlled study reported that patients more likely to respond to PA coaching interventions were those patients with better preserved functional capacity (Demeyer et al. 2017). Some of our patient population were perhaps too frail to benefit maximally from the proposed PAI.

PR aims to increase quality of life and exercise capacity (Bolton et al 2013). Both the CAT and ISWT are routinely used, and have demonstrated increases in line with their reported MCID (Dood et al 2011, Bolton et al. 2013). However in the current study, of those who adhered to the PR intervention only 44.9% met the MCID for CAT and 20% for ISWT. A recent PR audit in England and Wales reported 61% of patients reached the MCID of CAT and 57% for ISWT (Steiner et al. 2015). All our sites subjectively reported adhering to core components of the BTS guidelines but the fidelity of the PR was not assessed, as PR was viewed as usual care and therefore the control condition (Bellg et al. 2004). The NIH BCC guidelines for fidelity do not recommend assessing and monitoring the fidelity of the control condition (Bellg et al. 2004). A future trial will need to ensure that PR programmes are optimised before the trial commences, although it is understood that not all patients will respond to treatment; improving the quality of the service provided can impact on the benefits experienced by patients (Steiner et al. 2016).

The estimated time to deliver the PAI to eight patients individually across 12 weeks is 60.8 (34.4) hours. The estimated time to deliver a PR programme to eight patients in a group over 6 weeks is 24 hours. The LIVELY PAI takes approximately double the amount of time to deliver to eight patients compared to the PR, which would result in increased costs. However, there is a large SD in the predicted length of time to deliver the PAI to eight patients, and the PAI had a higher rate of adherence which has potential for cost saving implications in the longer term. Finally, we are comparing two different modes of treatment for people with COPD and there are opportunities to modify the PAI to reduce costs

and bring them more in line with PR. For example, using an online platform linked to the activity monitor whereby the step counts are automatically uploaded, so that the interventionist can review these before the consultation, would reduce costs. The number of face to face consultations could also be decreased; qualitative data from the current trial demonstrated that some participants felt they could have transitioned to this earlier (Chapter 4). It has been suggested that much of the coaching could be done using a telemedicine approach (Demeyer et al. 2017, Moy et al 2015), although not all trials were equally successful (Vorrink et al. 2016). Furthermore delivery in a group setting while retaining individual setting of step goals could decrease the time taken to deliver the PAI. In addition the phenotype of patients preferably referred to conventional PR or to PAI may be different

The feasibility nature of this study limits our ability to draw conclusions about the effectiveness of this PAI in comparison to PR. The PR delivery was conducted as part of usual care, with no monitoring from the research team; a future trial should consider ensuring all PR sites included in the study are optimised prior to study implementation through to study completion. Strengths include the assessment of the fidelity of the PAI (Chapter 6) and all data recorded and analysed in this paper was assessed for accuracy.

3.4 Conclusion

All applicable NIHR criteria for the success of a feasibility study were met with important learning and information regarding recruitment, eligibility, outcome measures and the sample size for a future study identified. The mixed methods design has enriched the data and exploring patients' views and satisfaction has helped complement and verify the quantitative findings. The LIVELY PAI appears to be effective in improving step counts in people with COPD, feasible to deliver and had good fidelity. This study provides key information to inform a future RCT in PA.

Figures

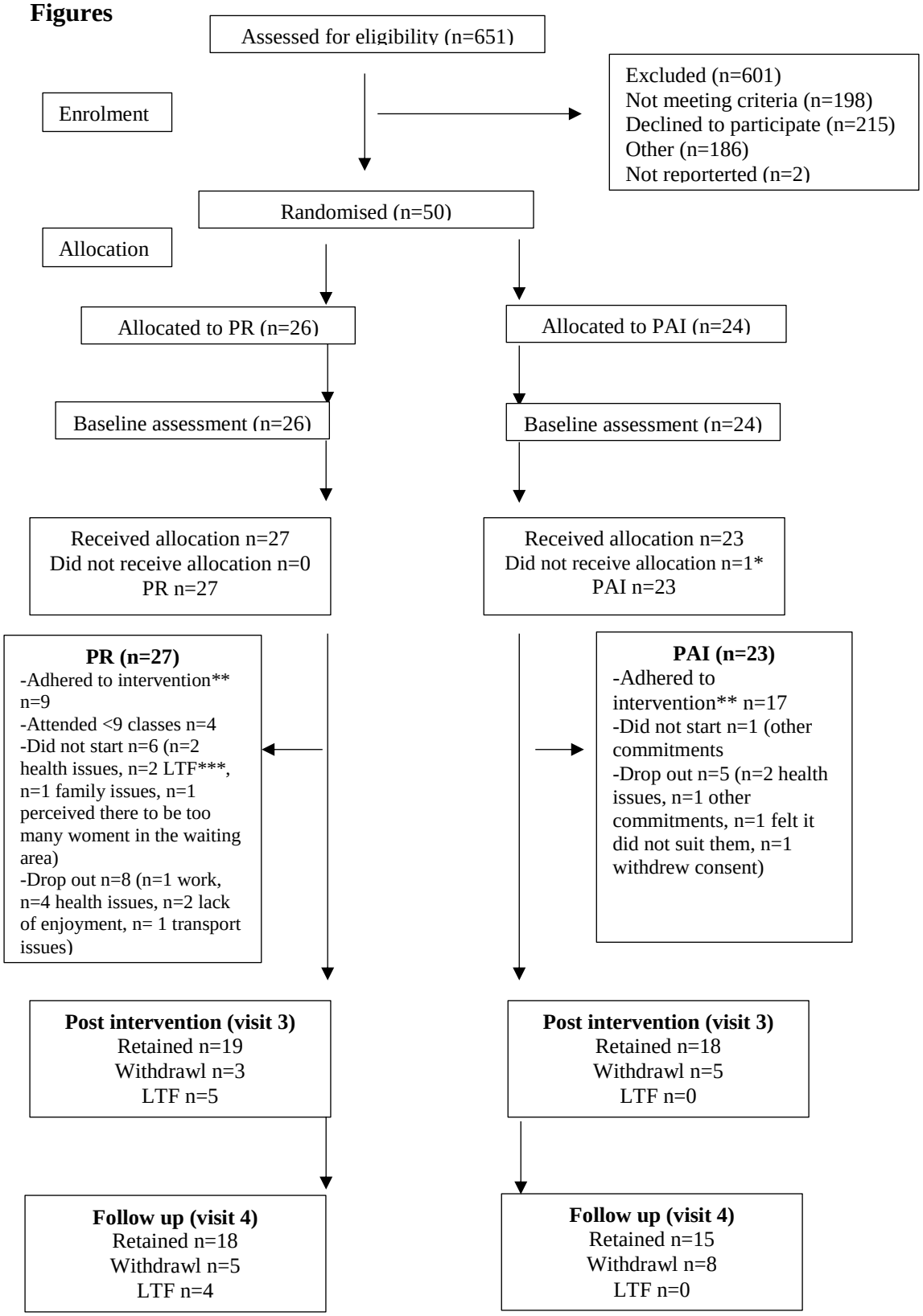

Figure 3-1 Flow of participants through the study and adherence to the PAI and PR *participant attended PR instead of PAI by mistake, **Adherence set at 75%, ***LTF= Lost to Follow-up

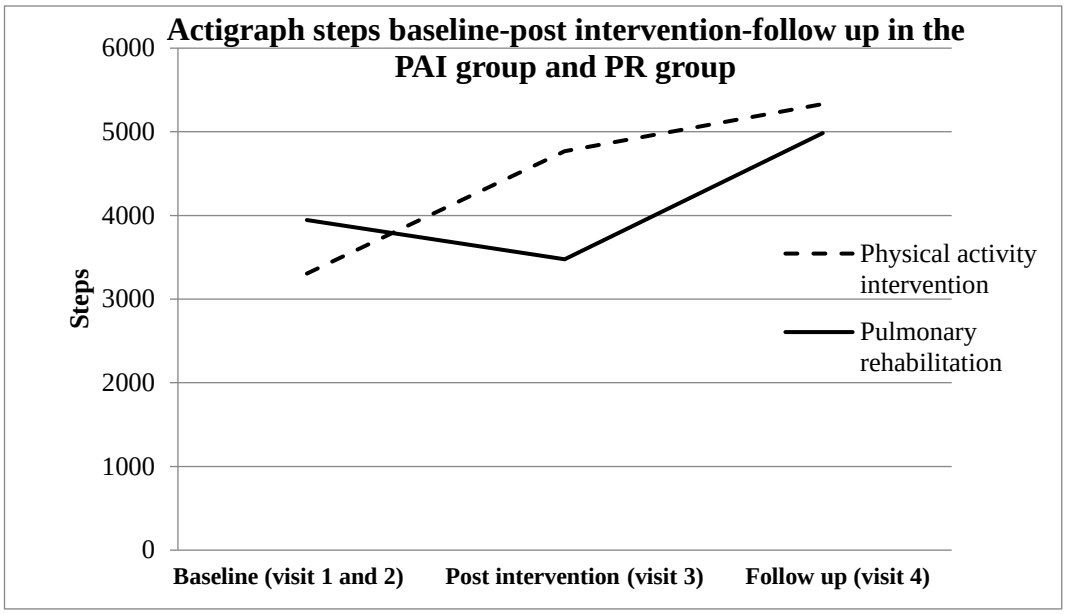

Figure 3-3 ActiGraph step count at baseline (visit 1 and 2), post intervention (visit 3) and at follow up (visit 4)

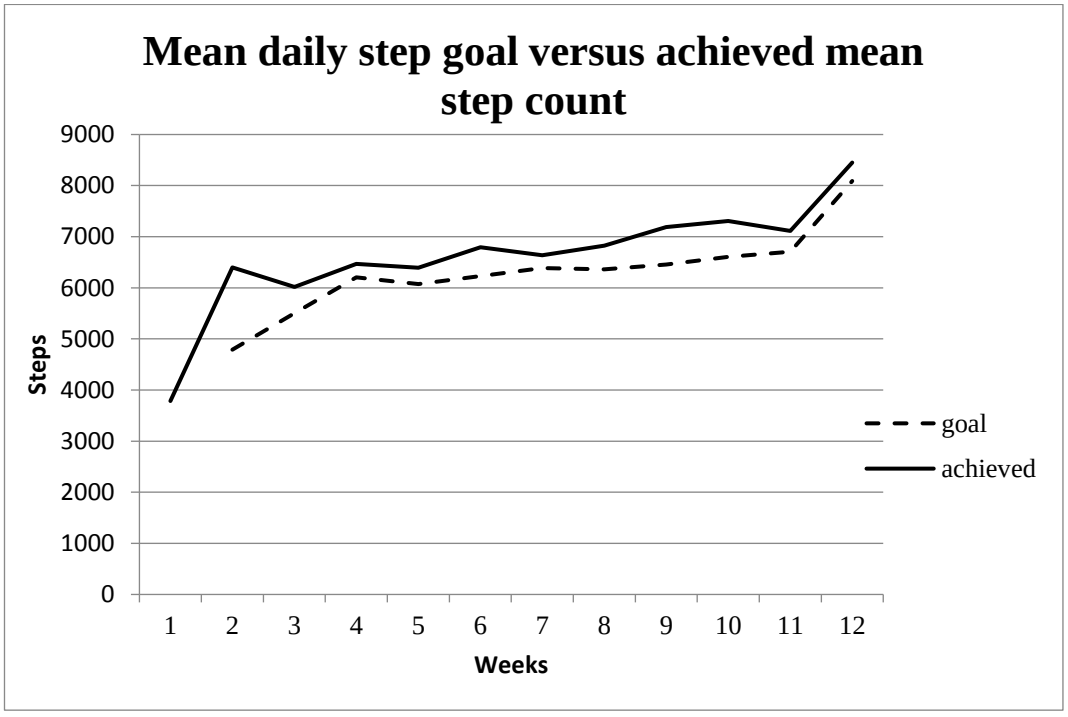

Figure 3-4 Mean daily step count goal compared to the step count achieved across the 12 weeks of the PAI [numbers of participants providing step count data at each time point varies due to attendance and withdrawals; familiarisation week1=21; week2 n=18; week3 n=19; week4 n=18; week 5 n=17; week6 n=18; week7 n=18; week8 n=17; week9 n=17; week10 n=17; week11 n=16; week12 n=3]

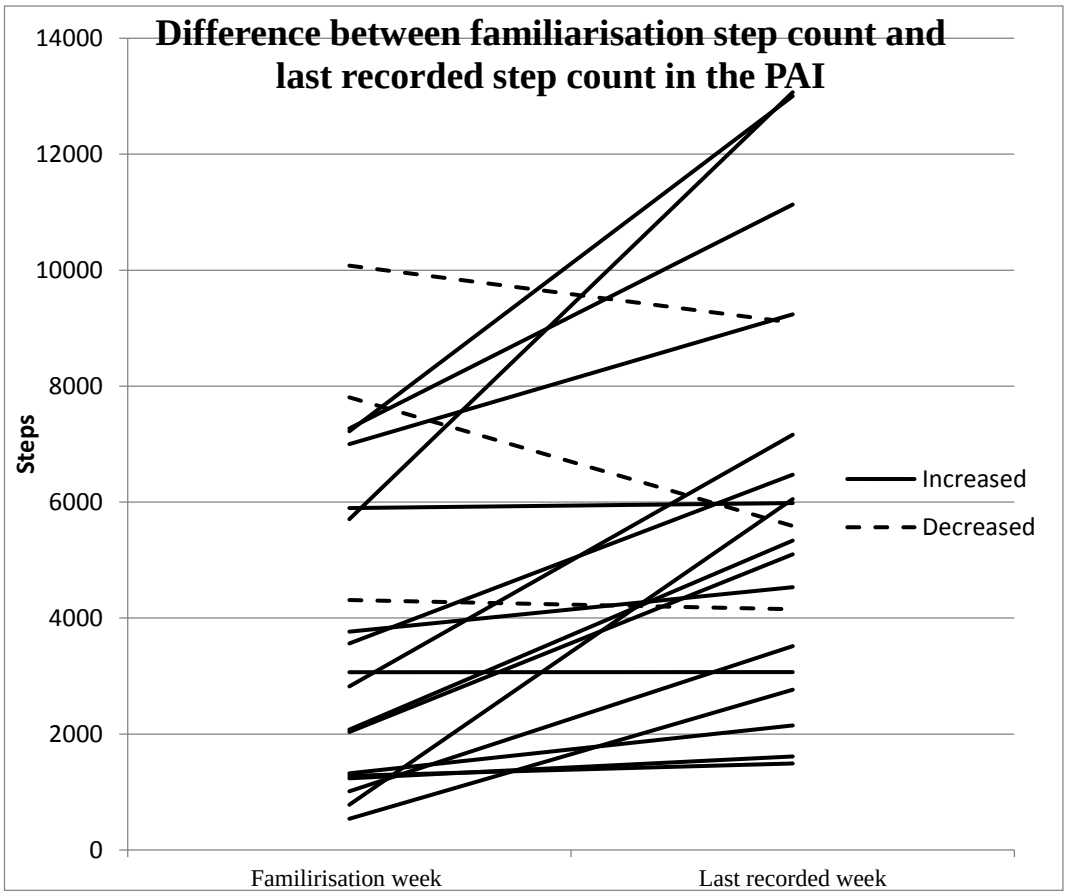

Figure 3-5 Difference between the mean daily step count for the familiarisation week and last mean daily step count available step count recorded with unsealed pedometer for all participants who provided a step count at two time points n=20 in the PAI.

Tables

Table 3-2 National Institute for Health Research Success Criteria for a feasibility trial*

Criteria	Present	Comment
Number of eligible patients.	✓	See Table 3.3
Willingness of participants to be randomised.	✓	Yes all patients were willing to be randomised; one participant attended the incorrect allocation.
Willingness of clinicians to recruit participants.	✓	See Table 3.3.
Characteristics of the proposed outcome measure.	✓	This has been reported.
Time needed to collect and analyse data.	✓	This has been reported in the main paper.
Follow-up rates, response rates to questionnaires, adherence/compliance rates.	✓	Figure 3-1and Table 3-5 details these.
Standard deviation of the outcome measure, which is needed in some cases to estimate sample size.	✓	Measures of variance reported

*relevant criteria only for this study included

Table 3-3 Screening data, reasons for exclusion from the LIVELY study in COPD

Exclusion criteria	Number of participants (n=601)
Not meeting criteria	**198**
COPD not primary Diagnosis	47
Unable to safely take part	120 [e.g. black outs, musculoskeletal problems, gait pattern means pedometer may not work, torn Achilles, fibromyalgia and 2 sticks for walking, chronic back pain, severe depression, cardiac issues/angina, epilepsy, intermittent claudication , wheel chair, long term oxygen therapy and use of a rollator],
Clinically unstable	19 [e.g. pulmonary exacerbation or any change in symptoms or medication in the last four weeks resulting in the patient being deemed clinically unstable by the clinical pulmonary rehabilitation team]
Unable to comprehend/follow instruction	8
Unable understand English	4
Declined to participate	**215**
wanted PR as planned	136
not interested in PR	44
other health issues perceived by patient	19
time commitments	5
unknown	4
unwilling to take part in research	2
family/carer/social reasons	2
unwilling due to additional assessments	1
wants different PR location	1
transport issues	1
Other	**186**
did not attend PR information session	87
unable to contact	43
lost to screening follow up	3
chronic pain	1
other	27 [e.g. awaiting lung surgery, wrong HSC number, already started PR]
deceased	2
referred to incorrect PR site	4
Did not attend outcomes assessment	4
Recruitment target reached for that PR site	15
Non reported	**2**
Total Excluded	**601**

Table 3-4 Baseline demographics and characteristics of participants

Baseline Demographic Characteristics	**Whole population N=50**	**Physical Activity Intervention N=23**	**Pulmonary Rehabilitation N=27**
Age (years)	64.14 (8.6)	61.09 (8.5)	66.741 (7.9)
Gender (m:f)	24:26	13:10	11:16
BMI (kg/m$^{2)}$	27.9 (6.9)	27.3 (7.4)	28.5 (6.7)
Medicine usage Respiratory medication only	7.8 (3.8) 3.3 (0.9)	7.2 (3.6) 3.5 (0.8)	8.3 (4.1) 3.0 (0.9)
Co-morbidities >= 2	30	N=9	N=21
Occupation (Frequency) Retired Unemployed Employed Other	 30 10 9 1	 12 7 4 0	 18 3 5 1
FEV_1 L/min Mean (±SD) GOLD classification Mild Moderate Severe Very severe Missing No classification	1.4(0.6)[n=50] 4 14 18 4 1 9	1.4(0.6)[n=23] 0 6 11 1 0 5	1.4(0.6)[n=27] 4 8 7 3 1 4
Long-term Oxygen therapy use (Frequency) Yes No	 6 44	 3 20	 3 24
Smoking history Never Ex Current	 2 38 10	 0 17 6	 2 21 4
MRC score (frequency) 1 2 3 4 5	 2 9 18 8 13	 1 3 7 6 6	 1 6 11 2 7

Mean (±SD), unless otherwise indicated
BMI- Body Mass Index
FEV_1- Forced Expiratory Volume in 1 second
MRC- Medical Research Council

Table 3-5 Available outcome measures at each time point and reasons for any missing data

Outcome Measure and reasons for missing data	PAI Baseline N=23	PR Baseline N=27	PAI Post intervention N=18	PR Post intervention N=19	PAI Follow up N=15	PR Follow up N=18
ActiGraph	Available N=17	Available N=24	Available N=14	Available N=12	Available N=12	Available N=14
Not meeting wear time criteria (5 days of ten hours)	N=3	N=3	N=2	N=2	N=2	N=4
Patient non-compliant with wearing device	N=1					
Researcher error in download	N=2		N=1	N=3		
Paper base outcomes only			N=1	N=1	N=1	
ActiGraph error				N=1		
Pedometer	Available N=22	Available N=21	Available N=16	Available N=13	Available N=10	Available N=13
Not meeting wear time criteria (5 days of 100-50,000 steps)		N=6	N=1	N=5	N=4	N=5
Patient non-compliant with wearing device	N=1					
Paper based outcomes only			N=1	N=1	N=1	
IPAQ	Available N=23	Available N=27	Available N=18	Available N=18	Available N=15	Available N=17
Unable/unwilling to complete				N=1		N=1

Table 3-5 Continued. Available outcome measures at each time point and reasons for any missing data

Outcome Measure and reasons for missing data	PAI Baseline N=23	PR Baseline N=27	PAI Post intervention N=18	PR Post intervention N=19	PAI Follow up N=15	PR Follow up N=18
GROC			Available N=13	Available N=13	Available N=11	Available N=9
Outcome measure added to CRF after visit was completed			N=4	N=5	N=4	N=8
Unable/unwilling to complete			N=1	N=1		N=1
CAT	Available N=23	Available N=27	Available N=27	Available N=19	Available N=15	Available N=18
Not available in CRF			N=1			
EQ5D5L	Available N=23	Available N=27	Available N=18	Available N=19	Available N=15	Available N=17
Unable/unwilling to complete						N=1
ISWT	Available N=23	Available N=27	Available N=16	Available N=16	Available N=14	Available N=17
Paper based outcomes only completed			N=1	N=1	N=1	
Unable/unwilling to complete			N=1	N=1		N=1
Removed- outlier				N=1		
Marcus Self-efficacy	Available N=23	Available N=27	Available N=17	Available N=18	Available N=14	Available N=17
Unable/unwilling to complete			N=1	N=1	N=1	N=1

IPAQ- International Physical Activity Questionnaire; GROC- Global Rating of Change; CAT- COPD Assessment Test; ISWT- Incremental Shuttle Walk Test

Table 3-6 Results of participant outcome measures (ActiGraph, Sealed pedometer, IPAQ) for the PAI group and PR group at baseline and post intervention. (Mean (SD) [CI])

Outcome measure	Baseline PAI (n=23)	Baseline PR (n=27)	Post PAI (n=18)	Post PR (n=19)	Post intervention-baseline PAI	Post intervention-baseline PR
ActiGraph	**N=17(*n=3,Σn=1,®n=2)**	**N=24 (*n=3)**	**N=14(*n=2,®n=1,Σn=1)**	**N=12 (*n=2, ,®n=3, Σn=1, βn=1)**	**N=12**	**N=11**
Step count	3305.6 (1960.2)	3946.2 (2263.1)	4768.2 (2992.1)	3476.6 (2307.9)	972.0 (3230.2) [-1080.3 to 3024.4]	4.3 (662.7) [-440.9 to 449.5]
Total MVPA time (mins/day)	14.3 (15.3)	14.6 (15.3)	24.49 (26.0)	12.80 (20.0)	6.6 (26.8) [-10.4 to 23.7]	0.9 (6.0) [-3.2 to 4.9]
MVPA $_{10+}$ number of bouts	0.05 (0.1)	0.1 (0.2)	0.57 (1.1)	0.01 (0.04)	0.5 (1.0) [-0.2 to 1.1]	-0.03 (0.1) [-0.1 to 0.05]
MVPA$_{10+}$ time (mins/day)	0.87 (2.0)	1.3 (3.0)	11.67 (21.5)	0.1 (0.4)	9.1 (20.2) [-3.8 to 21.9]	-0.4 (1.4) [-1.3 to 0.5]
PA category sedentary	N=14	N=17	N=10	N=11		
PA category Low active	N=2	N=5	N=2	N=0		
PA category somewhat active & above	N=1	N=2	N=2	N=1		
Pedometer	**N=22 (Σn=1)** 3044.4 (1871.1)	**N=21 (*n=6)** 3387.2 (1942.8)	**N=16 (*n=1, π n=1)** 5570.7 (3486.7)	**N=13 (*n=5, π n=1)** 3917.5 (2194.9)	**N=16** 2310.3 (3614.7) [384.2 to 4236.4]	**N=13** 146.9 (1605.7) [-823.4 to 1117.2]
IPAQ Total PA level (MET/ mins/week)	1464.1 (1553.3)	1734.0 (1692.6)	2427.7 (1559.7)	**N=18 (Σ n=1)** 2229.9 (2189.9)	**N=18** 907.5 (2270.5) [-221.6 to 2036.6]	**N=18** 547.5 (2765.5) [-827.7 to 1922.8]
IPAQ category - Low	8	10	2	7		
IPAQ category Moderate	13	10	11	7		
IPAQ category - High	2	7	5	4		

IPAQ International Physical Activity Questionnaire; MVPA Moderate Vigorous Physical Activity. *Not meeting criteria. Σ patient non-compliant with wearing device ® researcher download error.π: paper based outcomes only completed. β ActiGraph error, α: unable/unwilling to comple

Table 3-7 Results of participant outcome measures (GROC, ISWT, CAT, EQ5D5L) for the PAI group and PR group at baseline and post intervention. (Mean (SD) [CI])

Outcome measure	Baseline PAI (n=23)	Baseline PR (n=27)	Post PAI (n=18)	Post PR (n=19)	Post intervention-baseline PAI	Post intervention-baseline PR
GROC *Worse* *Better* *No Change* *N/A*			**N=13 (αn=1, #n=4)** 1 12 0 0	**N=13 (αn1, #n=5)** 2 8 2 1		
ISWT Distance (M)	253.0 (118.8)	254.81 (139.8)	**N=16 (α n=1, π n=1)** 288.1 (107.0)	**N=17 α (n=1, π n=1, **n=1)** 280 (139.7)	**N=16** -11.9 (90.4) [-60.1 to 36.3]	**N=16** -7.6(69.9) [-43.6 to 28.3]
CAT	23.8(6.9)	19.4 (8.0)	**N=17 (Ω n=1)** 22.5 (7.0)	16.6 (5.3)	**N=17** 0.6 (7.7) [-3.3 to 4.6]	**N=19** -0.4 (6.4) [-3.5 to 2.7]
CAT severity *(frequency)* V high (>30) High (>20) Medium (10-20) Low (<10)	 5 10 8 0	 2 12 10 3	 1 10 5 1	 0 3 14 2		
EQ-5D-5L Weighted Health Index	0.5 (0.2)	0.6 (0.3)	0.5 (0.3)	0.7 (0.2)	**N=18** -0.003 (0.2) [-0.1 to 0.1]	**N=19** 0.1 (0.2) [-0.02 to 0.2]
EQ-5D-5L Health state VAS	56.2 (20.8)	61.0 (18.9)	58.6 (23.0)	74.0 (19.9)	**N=18** 2.6 (35.2) [-14.9 to 20.1]	**N=19** 13.3 [-0.9 to 27.4]

GROC Global Rating of Change; CAT COPD Assessment Test. π: paper based outcomes only completed. α: unable/unwilling to complete, # outcome measure added to CRF post visit Ω Outcome measure not available in CRF, **outlier

Chapter 4 - Patients perceptions of a PAI and of PR in the LIVELY COPD project

4.0 Chapter Overview

This chapter reports the methods and results of the qualitative component of the LIVELY COPD project (Chapter 3) which used a mixed methods approach. Five researchers were involved in conducting this qualitative research and each member had a specific role as outlined in the Table 4.1.

Table 4-1 Role of members on the study team

Personnel	Role
Orlagh O'Shea	-Development of protocol for analysis of qualitative component -Development of semi structured interview script -Conducted semi structured interviews -Carried out qualitative analysis - Drafted results - Completed write up of chapter
Prof. Judy Bradley	-Development of protocol for analysis of qualitative component -Development of semi structured interview script. - Carried out qualitative analysis - Drafted results -Contributed to the intellectual interpretation of results and write up of chapter
Dr Brenda O'Neill	-Development of protocol for analysis of qualitative component - Development of semi structured interview script -Conducted semi structured interviews - Contributed to the intellectual interpretation of results and write up of chapter
Dr Adele Boyd	-Conducted semi structured interviews
Prof. Suzanne McDonough	- Contributed to the intellectual interpretation of results and write up of chapter
Prof. Madelynne Arden	-Development of semi structured interview script
Alanna Rogan	-Quality checks during analysis
Natasha Greene	-Quality checks during analysis

4.1 Introduction

Qualitative research is increasingly conducted within feasibility studies (O'Cathain et al. 2015). Obtaining patient perspectives through qualitative research can help to fully explore the workings of each treatment arm and address any uncertainties or limitations within the design prior to commencing a future randomised controlled trial. Therefore a qualitative research component was included as part of the LIVELY COPD feasibility project (Chapter 3). The importance of mixed methods research has been emphasised in the MRC guidelines, as it allows greater understanding of patients' perceptions, for example barriers to participation (Craig et al. 2006), which in the context of a feasibility study can help understand problems with adherence and retention before progressing to a future trial. Additionally, in some instances the qualitative data can demonstrate a favourable effect on health outcomes where quantitative methods have failed (Moffat et al. 2006). Conversely, patients' views and perspectives are important, for example, even if the quantitative outcomes showed a favourable effect, if the intervention was unacceptable to the participants then there would be little support for moving forward to a future trial.

There is a small body of available research investigating patients' views about PR (de Sousa Pinto et al. 2013). In 2013 de Sousa Pinto et al. published a review of qualitative literature exploring patients' views of the impact of PR on their lives. Eight articles were included in this review and five main themes were identified: (i) support during PR, (ii) learning process through education, (iii) opportunity through health transition, (iv) barriers, difficulties and negative points, and (v) the benefits of PR. This review found that there are a number of beneficial aspects of PR; patients appeared to welcome the support from peers and health professionals in the programme as well as the educational aspect of PR. Patients also recognised PR as an opportunity for change and which enabled them be more optimistic about the future. The difficulties and negative aspects of PR themed in this review included transport difficulties, lack of support during the programme and lack of clarity in the information leaflets given. Some participants perceived the lack of support once the programme had finished as an obstacle to maintenance. Gaining an insight into patients' lived experiences like this has been recognised as an important step in optimising healthcare (Department of Health 2000). Qualitative research in PR has been used to help inform the current BTS PR Guidelines

(Arnold et al. 2006, Fishcer et al. 2007, Harris et al. 2008, Bulley et al. 2009, Bolton et al. 2013).

It is evident that PA is fundamental for the prevention of chronic disease and premature mortality (Min-Lee and Skerrett 2001). As such, there is a large body of literature exploring PAIs in various populations, including, for example, older adults, colorectal cancer patients, people with multiple sclerosis, mental health problems and COPD patients (King et al. 1998, Pilutti et al. 2014, Hubbard et al. 2016 Williams et al. 2016, Wilson et al. 2014). Researchers have explored participants' perspectives of participating in PAIs in these populations (Franco et al. 2014, Hubbard et al. 2016, Learmonth and Motl 2016, Mason and Hotl 2012). However, to date there is no qualitative research exploring COPD patients' views and experience of a PAI.

4.1.1 Aim

The aim of this study was to explore the participants' views and experience relating to their satisfaction and the benefits of a PAI and of PR.

4.1.2 Objectives

(i) To conduct semi structured interviews with all participants in the LIVELY COPD project in both the PAI and PR following the completion each intervention;
(ii) To transcribe and analyse the interviews from both groups separately using Kings Template Analysis as a framework (King 1998) and
(iii) To report on the results of the analysis, comparing the PAI and PR where applicable.

4.2 Methods

This qualitative study recruited patients from the LIVELY COPD project (Chapter 3); a randomised controlled mixed methods feasibility study. All patients who were recruited to the LIVELY COPD project were invited to complete individual face to face interviews at their post intervention assessment (visit 3) facilitated by a semi structured interview guide (Table 4.2). Interviews were conducted in a quiet clinical room at the study site. Ethical approval was obtained from the Office of Research Ethics in NI, Rec reference:

13/NI/0014, IRAS project ID: 107423 (Appendix 9, Ethical Approval from the Northern Ireland Research ethics committee). Written informed consent was obtained from each patient as part of the LIVELY COPD project and again verbally prior to each interview. The write up adheres to the consolidated criteria for reporting qualitative studies (COREQ) guidelines (Tong et al. 2007)

4.2.1 Data collection

A schedule for the semi structured interviews was developed by the project team in line with the main aims of the study, focusing specifically on exploring the participants' views and experience relating to their satisfaction and the benefits of a PAI and of PR. The semi structured interview schedule was developed during the design phase of the LIVELY trial. The current research regarding the COPD population, PR and PA were used to inform the focus of the semi structured interview. The health psychologist (MA), involved in supporting the intervention was also consulted during the development of the semi structured interview schedule. As the transcripts were being analysed minor amendments were made to the prompts associated with the interview schedule to better capture the aims of the study. Table 4.2 provides an outline of the interview schedule. The full semi structured interview schedule is available in the appendices; (Appendix 15, Semi Structured Interview Script on CD ROM). Interviews were conducted by independent outcome measure assessors (OO'S, BO'N and AB) who were not involved in the delivery of either the PAI/PR, to limit bias (Appendix 16, Qualitative analysis research team: credentials, training and/or experience).

4.2.2 Data analysis

Interviews were audio recorded and transcribed verbatim by OO'S and an administrator. Interviews were analysed using Template Analysis as described by King 1998. Previous publications in healthcare that have used this approach were referenced for guidance (McCluskey et al. 2011, King et al. 2002). Firstly, members of the team (OO'S, JB and BO'N) agreed to a priori themes; these themes were drawn from the questions in the semi structured interview schedule and at all times the aim of the qualitative research was kept in mind (Appendix 17, A priori themes for qualitative component of the LIVELY COPD project). At commencement of analysis, OO'S and JB analysed 25% of the transcripts from each group independently. All relevant text was attached to a code, if there was no

relevant theme or subtheme, a subtheme was added to an existing theme. Following the analysis of these transcripts, the initial template was developed (Appendix 18, Initial template for qualitative component of the LIVELY COPD project). OO'S then analysed the remaining transcripts with this template assigning all relevant text to the appropriate theme and amending the template as required throughout (Appendix 19, Amended of initial template for qualitative component of the LIVELY COPD project). During the analysis, the relevant text from each transcript was tabulated under the appropriate theme; a table was produced for each individual transcript. When all transcripts had been analysed, the tables were printed and the hard copies divided so as each theme and corresponding quote was separate. The themes with the associated relevant text were then pasted into a folder so that each theme and the relevant quotes from each individual transcript were held together. A separate folder was produced for the PAI transcripts and for the PR transcripts.

4.2.2.1 Quality checks

King 1998 advocates that quality and reflexivity checks are carried out during analysis of the transcripts. In this study, once all the transcripts had been analysed, the transcripts from each group were then re-read, (by OOS or JB) with the amended initial template to ensure that all aspects of the interviews were included. When all the transcripts had been re-read OO'S and JB met and discussed their findings and no further changes were made to the template.

In a further effort to enhance the validity and quality of our work, two colleagues (AR and NG), not involved in the project but with knowledge in this subject area, were each given 3 transcripts; (AR 3 PR transcripts and NG 3 PAI transcripts) and were invited to generate themes independently. This was completed without any advance exposure to the template (Appendix 16, Qualitative analysis research team: credentials, training and/or experience). No new additional themes were created and there was largely agreement between the researchers. There were some minor agreed changes to the template, for example the subthemes of respiratory and general health were collapsed to physical health.

A flow diagram of the methods is available in Figure 4.1. The final template and corresponding quotes were used to write up results (Appendix 20, Final template for the qualitative component of the LIVELY COPD project).

4.3 Results

Fifty participants were recruited to the LIVELY COPD project (Chapter 3). Thirty two participants were available to complete interviews; n=16 PAI and n=16 PR (Table 4.3). A flow diagram of participants available for semi structured interviews is available in Figure 4.2. The mean (SD) length of time for each interview was 17 (7) minutes. Five core themes were identified (Perceived benefit and impact of PAI/PR, views of and satisfaction with PAI/PR, adherence to the PAI/PR, views about outcome measures, views about continuing exercise/PA) with a number of subthemes relating to each theme which are available in Table 4.4 Themes and subthemes.

4.3.1 Perceived benefit and impact of PAI/PR

The semi structured interview explored what benefits the participants in each group experienced. There were five common subthemes within the theme perceived benefits and impact of PAI/PR; physical health, mental health, social activity and social support and enjoyment.

4.3.1.1 Physical health

Participants in both groups experienced improvements in their physical health, expressing improvements in their respiratory health and increased functional ability. Respiratory health benefits were mainly in relation to breathlessness. Perceived improvements in physical health manifested in being able to complete activities of daily living such as cleaning or gardening with more ease and confidence.

> *"My breathing is better, I am able to control my breathlessness better, so yes I feel that it has done some good."* (M79 PAI)

> *"I think it does because I can do, you know, this shortness of breath is not with me as often or as much."* (F74 PR)

> *"Well at the start I wouldn't have even attempted hovering or dusting or anything. Now I am doing them all."* (M55 PAI)

> *"I can go out leisurely walking with my daughter and I found that where I would be going behind them and they were waiting on me always and saying come on and that, I felt that I could keep up a lot longer, not all the time though."* (F74 PR)

4.3.1.2 Mental health

The prevalence of mental health disorders in people with COPD including anxiety and depression has been documented in the literature (Maurer et al. 2008). PR has been shown to be effective in improving the symptoms of these comorbidities (Bolton et al. 2013). Participants in both groups reported improvements in their mental health.

> *"I think definitely because you're physically, you feel physically stronger and able to cope and then, obviously then it makes you feel much better within yourself"* (M58 PR)

> *"You know I could go out of here now and just cry and just say I need to get home, I need to get home as fast as I can. I reckon the programme has helped me. Because I had something to do, a goal to reach"* (F58 PAI)

4.3.1.3 Social activity and social support

Participants in both groups experienced social benefits from taking part in their respective programme, both in terms of improved social support from family and friends and their increased ability to go out and be more socially active. Support from family and friends was evident through family and friends noticing and commenting on improvements in their appearance or activity.

> *"Yeah my sister has, she says I am more…..getting out of the house more whereas before I wouldn't of bothered."* (F56 PAI)

> "*Yes, yes I have been out a couple of times where I wouldn't have been before."* (F77 PR)

> *"They said I was looking much better, you see it is weight wise too for I was only 6 stone when I came out of hospital so there is a whole other factors."* (F63 PR)

4.3.1.4 Enjoyment

Enjoyment in taking part in the programme was a perceived benefit for participants in both groups. Being able to achieve specific goals also seemed to make the PAI more enjoyable for some.

"Once I started to see that I was achieving my goals it became more enjoyable right." (M63 PAI)

"Yes, I enjoyed it, it taught me a lot about things you weren't doing and things you should be doing." (M61 PR)

4.3.2 Views of and satisfaction with PAI/PR

The semi structured interview schedule explored participants' views and satisfaction of their respective programmes. Overall, participants in both groups appeared satisfied with their respective programmes, however, there were components of both the PAI and PR that participants were more satisfied with than others. Sub themes within this theme include tailoring of content, frequency, duration and mode of contact, education and educational materials and suggestions for improvement.

4.3.2.1 Tailoring of the content of the PAI/PR to the individual

PR is delivered in a group setting and is traditionally less individualised in comparison to the LIVELY PAI which was delivered on a one to one basis. The PAI was designed to be personalised to the individual, driven by their baseline step count and personal goals. Participants in the PR group felt they had some degree of input into the class, for example, they could stop when they were tired and the exercises were progressed over the course of the programme. In contrast participants in the PAI felt they were fully involved in shaping the intervention for themselves.

"*I mean you were able to say, if you felt it too much you could stop."* (F67 PR)

"I didn't really have any input into it, it was just laid out to do warm up exercises first and then to do all the usual……The only difference was once you had been there two or three weeks the ups from half a second, or half a minute to a minute then a minute and a half then two minutes." (M76 PR)

"I would have to say 100%……. because I always, although [provider's name] always, this is face to face, although I set a goal per day steps, be it 10,000 or whatever it was" (M63 PAI)

4.3.2.2 Frequency, duration and mode of contact with provider or PR staff

Participants in the PAI group had once weekly contact with the provider for 12 weeks; the first 6 weeks were delivered face to face, followed by 5 weeks of telephone contact and participants then returned for a face to face consultation at week 12. Participants in PR had twice weekly contact for 6 weeks. Participants in both groups were generally satisfied with the duration of the frequency of contact; however there were a small number in each group who would have been willing to have increased frequency of contact and to continue the PAI/PR for longer. In the PAI there was also a general feeling that there was good balance between face to face and telephone contact; most participants felt that these first 6 weeks of face to face were needed to establish a relationship with the provider. Some participants had a preference for the face to face contact while others felt they could have transitioned to the telephone contact earlier. There were also a small number of participants in the PR group who felt that twice a week was too much and would have preferred increased flexibility in the timing of the class.

*"I think 12 weeks probably right partly"(*M67 PAI)

"Six weeks, I think was just perfect." (F74 PR)

"I could have come down a bit more often do you see but then he had other people to see to like you know." (C212 M61 PAI)

"...I think it was just right because then it takes you a while to get to know somebody and know there, and then [provider's name] she needs to know what I can do and what I can't do and you sort of work it out between the two of yous and how you are going to do this and in the end, I think it takes, it really does take about six weeks to get there in the end. (F57 PAI)

"Could have been done earlier." (M67 PAI)

"But I would have liked to have kept going." (M76 PR)

"I did think twice a week a bit much now....It was a lot for me.....Maybe once a week. I would think now that's only for me.....I find it....everybody mightn't be the same as me but I am very busy two days a week and I go to another wee class on a Wednesday as well." (F67 PR)

4.3.2.3 Education and educational materials

Participants in both groups received disease specific education in line with the BTS guidelines (Bolton et al. 2013) and participants also received an information booklet (LWWCOPD) (Cosgrove et al. 2013). In the PAI, the education component was delivered one to one. In PR, education was delivered in a structured format to the group. The education was generally viewed positively in each group. Many participants appeared to find the education surrounding management of breathlessness and inhaler technique helpful. Most patients perceived the material in the LWWCOPD for PR booklet to be useful as reference point. However some participants were ambivalent towards the booklet and only read it in parts. A small number of patients in PR did not perceive the education to be relevant to them.

> *"I thought the inhaler technique was a bit of a revelation, ok compared to what I thought I knew and what he actually taught me was very, very good.* " (M63 PAI)

> *"All the reading material, everything was absolutely brilliant and anything you are not sure of you just go back to the book and just refresh yourself….."*(F67 PAI)

> *"I did aye, I felt they helped as well. Just coping with your breathing and difficulty breathing and stuff like that and proper use of inhalers which I wasn't aware I wasn't using it properly cos I was using them how I was shown to use them ya know."* (M58 PR)

> *"I don't use oxygen, they talked about oxygen I don't use oxygen and other medications that, you know didn't apply to me but at the same time they talked about a lot….."* (F77 PR)

4.3.2.4 Suggestions for improvement

Suggestions for improvement of each programme were identified by some participants. For the PAI, suggestions for improvement included: wanting more educational content and another individual felt the programme should account for other forms of PA. Participants also suggested holding the PAI in the summer and some follow up contact with the interventionist. Some suggestions for improvement in the PR group related to increasing the intensity or difficulty of the exercises and one participant felt that walking could have been included as part of the programme.

> *"….but there are other ways of using energy other than walking. Well it seems to not to have been taking into consideration…..Yeah I just perhaps feel that if somebody is doing something else on top of the walking that is perhaps not*

acknowledged or understood and that means that, it gives you a bit of a false idea of what somebody is doing." (F63 PAI)

"Well I, I feel that I probably could have done a bit more than what they were offering but obviously, it's obviously a, it's mixed levels of ability there. There's people that were a lot worse than myself, you know what I mean?" (M58 PR)

4.3.3 Adherence to the PAI/PR

Low levels of PA and low levels of adherence to PR have been reported in the literature in the COPD population (Watz et al. 2009, Steiner et al. 2016). Therefore this qualitative work aimed to explore what enabled the patients to adhere to their programme (facilitators) and any reasons for non-adherence (barriers).

4.3.3.1 Facilitators for adherence to the PAI/PR

A number of facilitators were identified in each group that enabled adherence and also enhanced performance in the respective groups. Common facilitators included intrinsic motivation, the staff/interventionists and social support. PAI specific facilitators included the pedometer, as well as the action and coping plans, a number of participants in the PAI group also developed their own specific strategies to facilitate adherence. The group setting was a facilitator specific to the PR group.

4.3.3.1.1 Intrinsic motivation

Patients' participation in the PAI and PR was intrinsically facilitated through their own motivation; some participants felt they were naturally quite motivated individuals.

"……..you know so I would drive myself. I would be a naturally driven person so if I agreed in the programme that I was going to do whatever I was going to do." (M65 PAI)

"Pushed me hard and that's what I said to them, push me hard and I want to feel it that I come out of here, that I am a wee bit sore that I know that I done me job.." (M79 PR)

4.3.3.1.2 Social support

Social support from family and friends was a common facilitator in enabling participants in both groups to take part in the programme. For example in the PAI group, one participants' friends stopped offering them lifts as they were aware they

were taking part in the programme and in the PR group another participant was supported through their church group.

> *"Ah none of them will give me a lift now because I have told them all not to stop to give me a lift. So I have to walk everywhere now.*" (M47 PAI)

> *"Well I have done quite a bit because we have another church group on a Tuesday night and it's called fit for life and the people that can't walk, the idea is you walk and pray or you walk and talk and if you can't you stay in the building. They had a video but it was too fast for me so I was doing some of these and I was introducing them to some of my exercises which was good, you know the wall press ups the sits and the mini squats you know."* (F73 PR)

4.3.3.1.3 Staff/providers

The staff delivering each intervention was a common facilitator for each group; encouraging participants and the relationship that developed across the intervention helped participants to fully engage in their respective programme.

> *"In the initial stages and the fact that you were going to meet [provider's name] and the fact that he was taking this with the due diligence which was required and you felt it was important to do the same thing, therefore it was important in the initial stages."* (M63 PAI)

> *"And these people that done this, everyone is encouraging, they've got personality, they have got everything and they made you feel as if you were alive and you hadn't got what you have."* (M79 PR)

4.3.3.1.4 Pedometer and action and coping planning (PAI specific)

Most participants in the PAI felt the pedometer facilitated their PA. Being able to monitor their PA with direct feedback was a key facilitator. Setting an action and coping plan with a specific goal each week and achieving this goal also helped facilitate participants to engage in the programme and increase their PA levels. The action and coping plan was specific to each individual and allowed for flexibility in their PA. This facilitated participants' engagement in the PAI.

> *"……I found the pedometer particularly useful to drive me to the goals that I set myself."* (M65 PAI)

> *"…….I would go out of my way to make sure I achieved that or else I would have to have a very good reason that I could square with my own conscience…… you know why I didn't achieve the goal."* (M65 PAI)

"Well, being a diary……..you have to fill it in at appropriate times……..and there is no excuse for missing a time you know. It does drive you to do it and you get some satisfaction out of doing it like anyone who does keep a diary." (M79 PAI)

4.3.3.1.5 Individual strategies to increase PA (PAI specific)

During the PAI participants developed their own specific strategies to facilitate their adherence to the intervention and achieving their goals. For a small number of participants in the PAI group, the sense of achievement they experienced when they reached their goals facilitated their participation. Participants were also encouraged to reward themselves if they achieved their goal.

"It's what….when, [provider's name] said to me about you should give yourself a treat if you do your walking, you give yourself a treat…….so I got my nails done which led to me getting my hair done which led to people saying how better I looked which I was so totally delighted about people thought I had actually went and got makeup and all done but it is just that, I think it improves the way you feel about yourself."(F57 PAI)

"……um today I parked in the farthest away car park and walked from level H down the stairs, I didn't take the lift, you know so my confidence …….it's just a confidence thing." (M65 PAI)

4.3.3.1.6 Group setting (PR specific)

The group setting of PR was a facilitator for some individuals who found themselves competing with and comparing themselves to others in the group, and this encouraged them to work harder, and further facilitated their engagement in the programme.

"Well you have to push yourself you don't get the same…….You're not sort of, not intentionally but when you are up there you're sort of competing against the other people." (M76 PR)

4.3.3.2 Barriers

Participants in each group reported a number of barriers to participation in their respective programmes. Barriers included physical and mental health, the weather/environmental factors, lack of social support, time/other commitments and for the PR group specific barriers included the group setting and motivation to do the programme independently.

4.3.3.2.1 Physical health

Participants in both groups often perceived their overall health as a barrier. In terms of respiratory symptoms, breathlessness appeared to inhibit their ability to be physically active. Often periods of ill health independent of their respiratory symptoms prevented participants in both groups from full participation.

> *"Even now as I was these last few days I wasn't well but I was still doing breathing and doing walking round the……because I couldn't put no speed on… Because I had an infection in my chest like. You know and I couldn't get out to do any walk…."* (M73 PAI)

> "*No, no if I didn't want to do it I wouldn't have done it. I just, you know. There was one day there, I got out of bed for a couple of minutes, I wasn't too well and I just got back into bed so I didn't use the pedometer at all that day, so."* (M47 PAI)

> *"Um sometimes the breathlessness would have put me off going out walking. So I hope to be able to go back to walking now after this."* (F77 PR)

> *"I missed one. No no. The one day I didn't come I just took violently sick. I had ate something obviously disagreed with me …"* (F62 PR)

4.3.3.2.2 Mental health (PAI specific)

Mental health problems have been reported as a barrier to adherence to exercise programmes in the COPD population (Heerema-Poelman et al. 2012). In the current study, mental health presented as a barrier to participation for a small number of participants in the PAI group only.

> "*I don't know. That sorted like….my mental state at the time to be honest. But if it is it will be really one or two days like it wouldn't disrupt the programme completely. It would just be that I am feeling down and I just have to go down and come up out of it."* (F63 PAI)

> *"Do you know what I mean. like I could get two days of cleaning the house and different things and then two days of just not moving, barely even feeding myself. I had a few wee spells of that. My moods go up and down, they are like waves up and down."* (F58 PAI)

4.3.3.2.3 Weather/environmental factors

The weather was a common barrier for both groups. The wind and rain or any adverse conditions often prevented a number of participants from being physically active, but did not specifically hinder adherence to the PR programme.

"No there always is a situation when walking into the wind and things like that would have been a bit of an issue." (M63 PAI)

"Yeah I hate the rain, I hate being out…… the wind would stop me walking as much. It catches the breath…." (F62 PR)

4.3.3.2.4 Lack of social support

Lack of social support was a common barrier to both groups. Some participants identified not having friends/family around to support their PA/exercise as a barrier.

"No you see I live on my own which probably doesn't help matters. So no." (F63 PAI)

"I think if I could go out and walk, it would mean a lot more to me, because I don't get to walk much and ……they are lonely places and I don't like walking on my own." (F74 PR)

4.3.3.2.5 Time/other commitments

Time and/or other commitments were a barrier in both the groups. For example, Christmas time was a particularly busy work period for one participant in the PAI group. In the PR group, barriers included other commitments such as work or general life; for example taking the car to the mechanic prevented one patient from participating fully in the programme; spouses taking ill or bereavements also presented as barriers to participation in PR.

"*I think, well I just felt it was done at the wrong time of year. I mean not just because of me and my craft shows at Christmas but because of the fact for anybody Christmas is a funny time you are out racing around one minute then you are lying about and then you get the bad weather."* (F63 PAI)

"…….and I do have a part-time job and if it didn't suit me on Tuesdays and Thursdays and I wouldn't come, so maybe more flexibility. You know. I am free on a Thursday so that doesn't matter but on a Tuesday I do children pick up at 3.00 pm so I always have to leave early on a Tuesday." (F60 PR)

4.3.3.2.6 Group setting (PR specific)

Although a number of participants found the group setting to be very beneficial, others did not enjoy this aspect of PR and it served as a very strong barrier to participation for those individuals. For example this was the reason for withdrawal for a few patients who did not enjoy the group setting.

"I only went for one session because I found that I didn't feel as bad as what some of the other people actually looked. They were wearing oxygen tanks and you know I just didn't feel that I was that bad to warrant pulmonary rehabilitation." (F58 PR)

"Well it wasn't, oh dear. It wasn't the programme I found that the people on the course were in my opinion very self-obsessed with their own conditions and it drove me……. I just couldn't hack it. ……..which is naughty but that's really why, nothing to do with the physios or the exercises." (M72 PR)

4.3.3.2.7 Motivation to do the programme independently (PR specific)

Some participants in the PR group expressed a lack of motivation to do the home exercise programme as a barrier. Participants found it difficult to motivate themselves outside of the class structure.

*"It's kinda easier coming to a class cos you know when you're coming to a class you just kind of have to do it. Whereas it's more difficult to sometimes to motivate yourself to do it, I mean I'll do it tomorrow…..it's easier to put it off. "(*M58 PR)

"….. you need somebody to drive you. You know you need somebody with a big stick to keep you at it." (F74 PR)

4.3.4 Views about outcome measures

A range of outcome measures were completed by participants at different time points. Participants wore activity monitors (containing an ActiGraph and a sealed pedometer) on a belt for 7 days, completed an exercise test (ISWT) and completed paper based questionnaires. Participants expressed their views about each of these outcome measures, as well as recommending how the outcome measure process could potentially be improved upon.

4.3.4.1 Activity monitors (worn on belt)

Participants' comments regarding the activity monitor belt (ActiGraph and sealed pedometer) were mixed. Some appreciated the objective nature of the measurement. Others participants found this cumbersome and did not enjoy wearing it and others did not mind wearing it.

".....you are able to see what I've been doing. You are not taking my word for it. Plus it is all sellotaped up and there is nothing you can do to…….you can't lie about it". (F57 PR)

"I thought they were very awkward……..They were very awkward when you were going to the toilet." (M68 PR)

"It was fine, it didn't, it didn't get in the way or anything. It was fine wearing it." (M58 PR)

4.3.4.2 Incremental shuttle walk test

The ISWT is an externally paced test of exercise capacity (Singh et al. 2008). Participants found it useful as a measure of their physical fitness and they could tell that they had improved. A few participants did not enjoy this test because it made them breathless or aggravated other comorbidities such as leg pain.

"I think that from the start until now I think, well I know I've improved I don't have to think that I know I'm 100% better than I was when you first did that walk……..because I didn't feel the pressure as much when I first started walking when we did it the first time I was shattered after half a dozen steps you know half a dozen after that you know where I felt this time I had progressed a lot better." (F67 PAI)

"A*s I say I have difficulties in my legs so sometimes I found it difficult to walk, but I just sort of past through it and just got on with it."* (M47 PAI)

"You know that walking I think it is a good test of how you can move and your breathing and all you know." (F73 PR)

4.3.4.3 Questionnaires

Some participants did not mind the questionnaires where others had a negative view, finding them complicated or difficult to understand, or felt they were vague or perhaps lacked repeatability.

"Um I think they were good," (F63 PAI)

".....all those questionnaires and all, they are a bit complicated. I thought they were all really, some of them weren't as complicated as others but....." (F57 PAI)

"I think that every time you would do them you might do them differently." (F77 PR)

4.3.4.4 Recommendations for the best method to test the effectiveness of the PAI/PR

Participants in both groups provided various recommendations on what they thought was the best way to measure the effect the PAI/PR had on their health. There was no common view on what was the best method to test the effectiveness of the PAI/PR. In the PAI group, one participant suggested conducting spirometry and another felt reviewing the providers' notes would be the best method to measure the effectiveness of PAI, while some felt that simply seeing how much they could walk now compared to the beginning of the programme was the best way to measure the effectiveness of the intervention. In the PR group, one participant felt that just asking their opinion would be the best way, another felt just seeing how far they could walk, while others felt the monitors or the walking test were the best way and were interested in their step count.

> *"Ultimately for me it is probably getting the spirometry test to see, look has there been an improvement in capacity."* (M63 PAI)

> "*Well the walking test…..the monitor is quite good, because at the end of the day it lets you know, and you know what you have done before."* (F67 PR)

> *"Yeah I think the belt one was very good. But I didn't wait to see the number of steps I was doing…….I would be interesting to see the results. My results from beforehand to after. I would say there might be similar steps……"* (F60 PR)

4.3.5 Views about continuing exercise/PA

Participants were followed up three months post intervention (visit 4). We explored with participants their views about continuing to exercise or to be physically active. There were two subthemes common to each group: plans for continuing exercise/PA and motivation and confidence to continue exercise/PA.

4.3.5.1 Plans for continuing exercise/ PA

A high number of participants in both groups planned to continue to be physically active and engage in exercise. Some had specific plans as to how they were going to achieve this. In the PAI group, some participants planned to engage in other activities while continuing with the programme on their own was a popular plan for others. In the PR group, participants planned on continuing the exercises at home, making a more conscious effort to be physically active, purchasing a pedometer and another participant

was keen to return to PR in the coming months to help him to maintain his exercise capacity.

> *"You know I will keep it up…..No I think this goal setting for the week, I mean I am up to now 45,500 steps per week. And over the next three months you would hope to get that up to, particularly coming into the summer months you would hope to get that up to 10,000 over the next three months, 10,000 per day."* (M63 PAI)

> *"I think it is sort of reinforcing how. Exercise is so accessible……..……you know in the home. As I said to one of the doctors… I said everybody has got a wall at home so you have no excuse not to do your ups and downs the wall. I have access to a lot of different classes outside and swimming and I am just realising there is a lot of stuff out there that is accessible to your level of fitness."* (F60 PR)

4.3.5.2 Motivation and confidence to continue exercise/PA

The benefits they achieved as a result of the PAI/PR provided the motivation and confidence to continue to engage with exercise and PA. Furthermore, most patients in both groups were confident they would continue; there was one participant in the PR group who had not adhered to the intervention who was not confident they would continue or perhaps even start to be physically active.

> *"Well if I let it drop I am going to end up back where I was at the start. And I don't want that back at the start I wouldn't have moved. Just sitting there. The only time I would move would be in to the kitchen to get a cup of tea."* (M55 PAI)

> *"So I knew that definitely the exercising must have been the thing that was doing me good because I wasn't doing anything else. I was on the same inhalers, the same…….stuff, you know that I felt more able to do things so I put it down to the exercising."* (F74 PR)

> *"On a scale of one to ten….probably a 9.5… confidence, I would put it at a ten but there might be deteriorations in my……for other reasons…*" (M67 PAI)

> *"Oh, at this moment in time I am very confident, I hope I don't fall by the wayside but I definitely do intend keep at it*." (F67 PR)

> *"Not very confident. I know that's bad*." (M72 PR)

4.4 Discussion

The aim of this study was to explore the participants' views and experience relating to satisfaction and benefits of a PAI and of PR. This qualitative research was a key component of assessing the feasibility of the LIVELY COPD trial. Participants' views and satisfaction of both the PAI and PR were explored, this provided key information on

the acceptability of the PAI and PR, which was not have available from the quantitative data. The barriers to participation and reasons for dropout were further explored. Patients' views on the outcome measures used and their plans for continuing PA/exercise helped to explain and verify some of the quantitative findings. The results of this qualitative research can be used to help inform a future study as well as future research in the COPD population. This is also the first study in COPD to explore patients' views of a PAI.

Participants in both the PAI and PR experienced a range of benefits and were generally satisfied with their respective programmes. Satisfaction and acceptability of the PAI is a core component of assessing the feasibility of a study (Bowen et al. 2009) and if the quantitative results showed a favourable effect but participants were dissatisfied, the feasibility of the future intervention would be questionable. Patients' views of PR in particular also reinforced the underpinning rationale that PR may not be suitable for all individuals, some participants in the PR group did not feel that all of the educational items were relevant to them or felt that they could have done more in terms of the exercises provided. Additionally, some of the PR participants did not feel that the programme was tailored to them; conversely the PAI group felt they were fully involved in shaping their intervention. Current National Health Service (NHS) policy on personalising medicine recognises that individuals with the same condition do not all have the same needs and advocates tailoring of treatment to the individual (NHS England 2016). Personalising healthcare can increase costs. Delivering the PAI on a one-one basis is more costly than delivering PR, based on the time taken to deliver each intervention, which is double that of the time taken to deliver the PR (Chapter 3). However this qualitative research has helped us consider areas where the cost could be reduced for a future study for example some participants in the PAI felt they could have transitioned to telephone contact earlier than at six weeks, so facilitating this earlier transition in a future trial or indeed in clinical practice would help reduce the cost of delivery. There were also higher rates of adherence and lower rates of drop outs in the PAI compared to PR (Chapter 3), which has the potential for cost saving in the long term. The high rate of dropout and nonattendance at PR results in an inefficient use of staff time and resources (Fischer et al. 2009). Finally, with the established benefits of higher levels of PA in COPD in terms of reduced hospitalisations (Moy et al. 2013), it is reasonable to hypothesise that personalising PA and exercise training in COPD patients could result in reduced costs in the longer term.

High rates of drop out were observed in the LIVELY COPD project (Chapter 3). This qualitative research provides important information on adherence to the PAI and to PR. Adherence was explored with all participants in terms of barriers and facilitators. There were common barriers to participation in both groups including health, the weather/environmental factors, lack of social support and time/other commitments which have been reported elsewhere (Thorpe et al. 2014, Arnold et al. 2006, Keating et al. 2011). Interestingly the group based delivery of PR was considered both a barrier and facilitator by different participants in this group, previous research has reported the group setting as a barrier to the uptake of PR (Harris et al. 2008), while de Sousa Pinto 2013 identified the group setting as a positive aspect of PR. This further supports the current evidence that PR is suitable for some but not all individuals with COPD and reinforces the need for increased choice for individuals with COPD to increase their exercise/PA levels. A future trial could consider a preference RCT to allow participants to choose or express their preference for which group they feel would best facilitate their needs and lifestyle. A recent feasibility study by Chaplin et al. 2017 compared a web based PR programme to conventional PR, the authors explored participants' preference prior to randomisation but did not allocate patients according to preference. The authors found that those who were younger and less disabled would have preferred the web based trial and older patients had a preference for the class. This is line with current literature; patients with coronary heart disease who are still working prefer a home based class (Grace et al. 2005). Therefore exploring patient preference and randomising accordingly could help overcome barriers and reduce dropout.

Patient views on outcome measures were mixed. There were no clear views on outcome measures which could help inform a future trial. However the qualitative exploration indicates that the outcome measures used may not have been optimal, in helping detect change. Quality of life in the current study was assessed with CAT and EQ5D5L and other questionnaires, including IPAQ (long form), stages of change, Marcus self-efficacy questionnaire and the global rating of change were also completed. Some participants found the questionnaires complicated and lacking repeatability, stating that every time you complete them you might answer them differently. A future study should consider reducing the number of questionnaires, taking into account the objective findings, the removal of the IPAQ, Stages of change, Marcus self-efficacy and stages of change would be advised. The stages of changes and self efficacy questionnaires could be incorporated

into the intervention as tools to help shape the intervention. Furthmore some patients found wearing the activity monitor belt (with the ActiGraph and pedometer) uncomfortable which may have impacted on the wear time. The use of one activity monitor is recommended for a future trial.

Nearly all participants expressed a desire and will to continue to engage in PA and exercise irrespective of group. The three month follow up (visit 4) quantitative data showed an increase in step count for both groups from baseline (visit 1 and vist 2) (Figure 2, Chapter 3). As part of the BCS employed in the LIVELY PAI, in the final consultation, providers discussed with patients their plans for maintenance; this may have aided their adherence to PA in the follow up period. Nonetheless this increase in step count was observed in both groups. The findings of this qualitative study in relation patients continuing to be physically active or engage in exercise can be mapped to elements of the Theory of Planned Behaviour (Azjen 1991), which has the potential to explain this increase in step count at three month follow up (visit 4). Patients *intended* to continue to be active, they expressed *positive attitudes* towards continuing to be active, the main reason for wanting to continue was due to the benefits experienced. In terms of the *perceived behavioural control*; a high number of participants expressed plans to continue to exercise in which they referred to the resources available to them, for example some participants planned to continue to use their pedometer or others planned on visiting the local health centre. Current research indicates that the benefits of PR start to diminish at 6-12 months (O'Neill et al. 2008, American Thoracic Society/European Respiratory 2006), participants in the current study were not followed up at this period but the follow up data at 3 months is encouraging (Chapter 3), demonstrating an improvement in step count from baseline. Both the BTS and ATS/ERS guidelines for PR recommend using cognitive behaviour therapy for behaviour change in COPD (Bolton et al. 2013, Spruit et al. 2013) and Mantanoi et al. (2016) recognise PA coaching as an effective method for increasing PA in people with COPD. Future studies should consider using the Theory of Planned Behaviour to help promote maintenance of PA and exercise in the COPD population. This theory has been previously shown to be a useful model to determine and predict exercise maintenance in other populations (Hasnan Ahmed et al. 2014).

There were some challenges in analysing the results of this reserach. The phrasing of some of the questions in the semi strucutred interview script allowed for, a yes/no

response from participants, which limited the interpretation of the data. This is important learning and a future trial should endeavour to phrase questions in an semi structured interview such that they do not elicit a yes/no response and allow the participant to express their views more easily.

4.5 Conclusion

In conclusion this is a novel study. Participants in the LIVELY COPD project experienced a range of benefits and were in general satisfied with their programme regardless of group allocation. This qualitative research was key in determining the feasibility of the LIVELY COPD project and helped verify and complement the quantitative results as well as providing suggestions for future research.

Figures

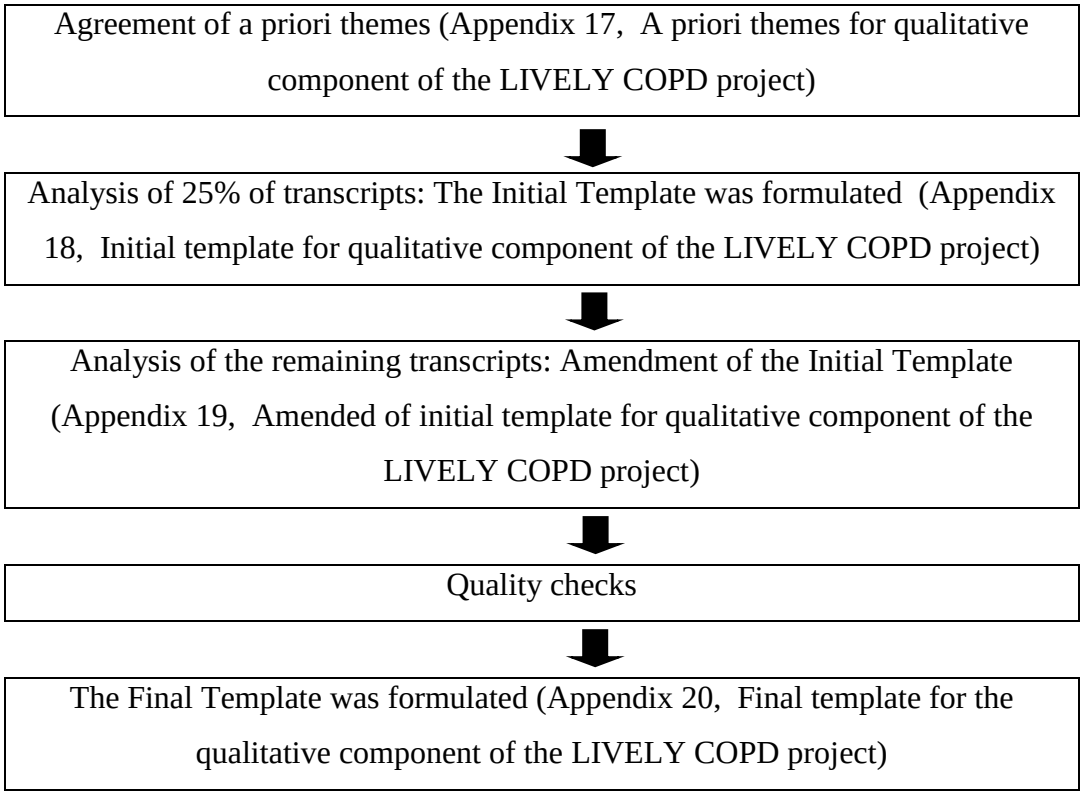

Figure 4-1 Flow diagram of methods for Template analysis (King 1998)

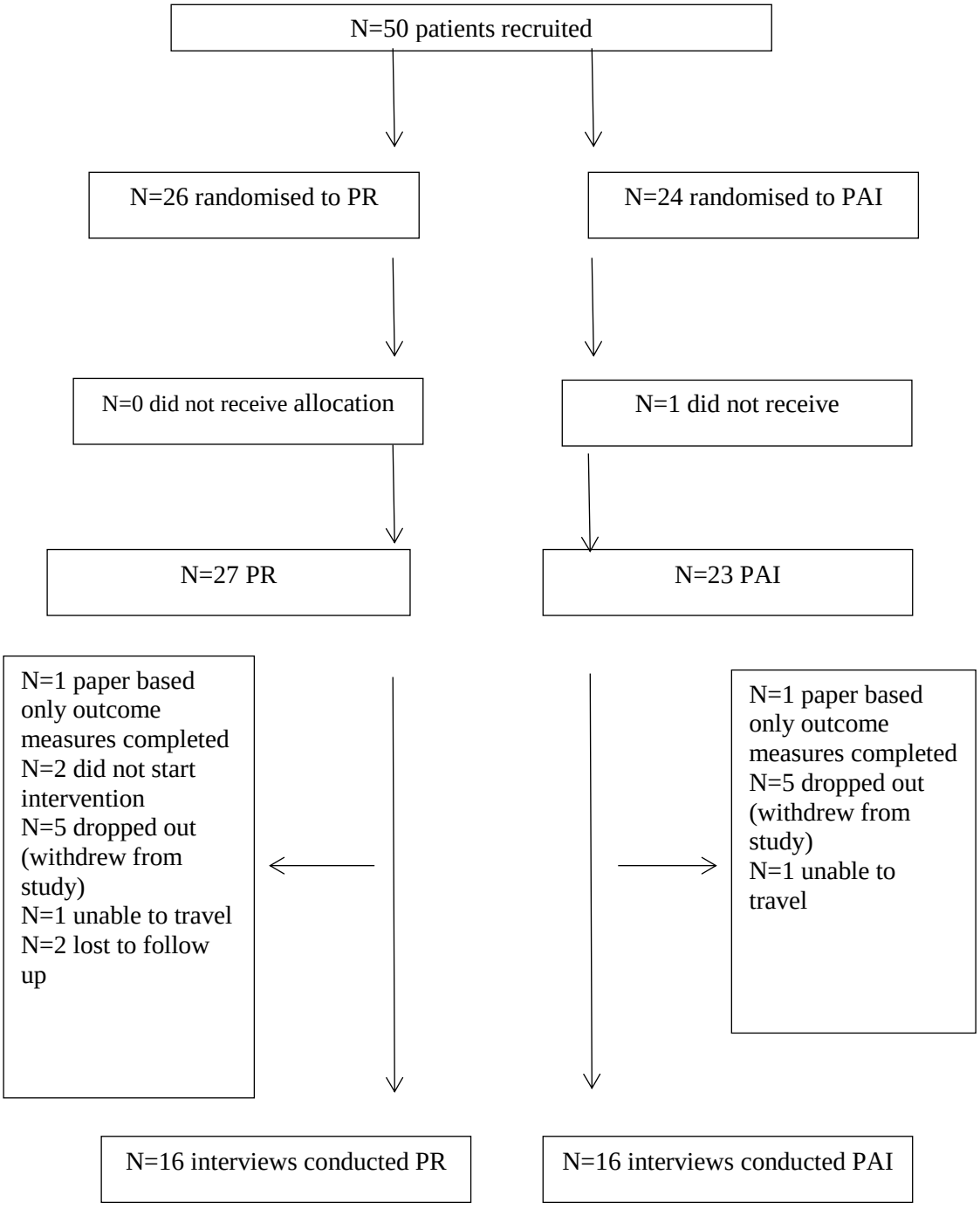

Figure 4-2 Qualitative research participant flow diagram

Tables

Table 4-2 Outline of the LIVELY COPD project qualitative semi structured schedule

Interview Schedule Questions
How do you feel the physical activity intervention / pulmonary rehabilitation programme has affected your health?
Do you think your relatives/carers/friends see a difference in you?
Do you think you have a good understanding of the benefits of exercise/PA for someone with COPD?
How satisfied were you with the: a. face-to-face physical activity intervention? b. pulmonary rehabilitation programme?
What suggestions if any, would you give to improve the physical activity intervention / pulmonary rehabilitation programme?
How involved did you feel in shaping the physical activity intervention / pulmonary rehabilitation programme, do you feel your level of fitness/ability was considered?
How easy did you find it to adhere to the physical activity intervention / pulmonary rehabilitation programme?
Have you ever done pulmonary rehab before?
This research wanted to test how the physical activity/pulmonary rehabilitation programme affected your health.
During the information collecting sessions with the researcher you wore two activity monitors for seven days at home, did a number of questionnaires and completed a walk test. How did you find these?
How confident are you that you could continue to exercise or do physical activity on your own now that the programme has finished?
Would you recommend the physical activity intervention / pulmonary rehabilitation programme to anyone else who has COPD? (optional question)
Is there anything else that you would like to add regarding your experiences of taking part in the study?

Table 4-3 Characteristics of participants completing the qualitative component of the LIVELY COPD project by group (n=32)

	Physical activity intervention n=16	**Pulmonary rehabilitation n=16**
Age	61.5 (8.5)	67.6 (7.8)
Gender	10M: 6F	7M:9F
FEV1%	59.7%	57.6% (27.0%)
GOLD classification		(n=31)
None	5	2
Mild	0	4
Moderate	5	3
Severe	6	4
Very Severe	0	2
Interviews conducted at visit 3	16	15
Interviews conducted at visit 4	0	1*
Others present at SSI	0	1**
Previous experience with PR	N=3	N=5

*missed visit 3 outcome measure assessment due to holidays ** participant's wife present at SSI

Table 4-4 Themes and subthemes for patients' views and perceptions of a PAI/PR in the LIVELY COPD project

Theme	**Subthemes**	
1. Perceived benefit and impact of PAI/PR	1.1Physical health	
	1.2Mental health	
	1.3Social activity and social support	
	1.4Enjoyment	
2. Views of and satisfaction with PAI/PR	2.1Tailoring of the content of the PAI/PR to the individual	
	2.2Frequency, duration and mode of contact with provider or PR staff	
	2.3Education and education materials	
	2.4Suggestions for improvement	
3. Adherence to the PAI/PR	3.1 Facilitators for adherence to the PAI/PR	3.2Barriers to adherence to the PAI/PR
	3.1.1Intrinsic motivation	3.2.1Physical health
	3.1.2Staff/provider	3.2.2Mental health
	3.1.3Social support	3.2.3Weather/environmental factors
	3.1.4Pedometer and action and coping planning (PAI specific)	3.2.4Lack of social support
	3.1.5Individual strategies to increase PA (PAI specific)	3.2.5Time/other commitments
	3.1.6Group setting (PR specific)	3.2.6Group setting (PR specific)
		3.2.7 Motivation to do programme independently (PR specific)
4. Views about outcome measures	4.1 Activity monitors (two worn on belt)	
	4.2 ISWT	
	4.3 Questionnaires	
	4.4 Recommendations for the best method to test the effectiveness of the programme	
5. Views about continuing exercise/PA	5.1Plans for continuing exercise/PA	
	5.2Motivation and confidence to continue exercise/PA	

Chapter 5 - Fidelity review: a scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions

5.0 Chapter overview

This review was undertaken to examine the most commonly used methods to assess treatment fidelity in the current literature to explore how treatment fidelity could be assessed in the LIVELY COPD project. This review was undertaken in collaboration with a Masters student (RMcC). The researchers involved in conducting this review and their roles are outlined in Table 5.1. The specific papers included in this review are referenced with "s" in this chapter, as the full results table is included in the appendices with this specific reference list attached (Appendix 21, Characteristics and reference list of included papers in the Fidelity review: a scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions). This review has been published, please see dissemination of findings page xiv.

Table 5-1 Role of members on the study team

Personnel	Role
Orlagh O'Shea	-Development of protocol -Conducted search of databases -Screened of title and abstracts -Assessed of articles for inclusion/exclusion -Data extraction -Synthesised results -Write up of chapter
Rosemary McCormick	-Development of protocol -Conducted search of databases -Screened of title and abstracts -Assessed of articles for inclusion/exclusion -Data extraction -Synthesised results
Dr Brenda O'Neill	-Development of protocol -Intellectual contribution to write up of paper/chapter
Prof Judy M. Bradley	-Development of protocol -Intellectual contribution to write up of paper/chapter

5.1 Introduction

The concept of treatment fidelity has evolved over time (Bellg et al. 2004); and there does not appear to be one single agreed definition. Treatment fidelity can refer to all the mechanisms that ensure an intervention tests its hypothesis and that all the components of the intervention are implemented as outlined in the protocol. There does however appear to be an agreement in the literature on the importance of assessing and monitoring treatment fidelity. Firstly treatment fidelity increases the internal validity of a trial such that the results of the trial are directly attributable to the intervention (Moncher and Prinz 1991). Good treatment fidelity also increases the reproducibility of the trial by enhancing external validity; this increases the extent to which the results can be generalised to the clinical setting (Bellg et al. 2004, Moncher and Prinz 1991, Resnick et al. 2005a). Additionally optimisation of fidelity can also increase the statistical power of an intervention as the varability in delivery has been minimised (Bellg et al. 2004, Resnick et al. 2005a, Spillane et al. 2007). If the results of an intervention are found to be non-significant and fidelity has not been monitored, it would be unclear if the results were due to an ineffective intervention or whether key elements of the intervention were not implemented as planned. Conversely lack of attention to treatment fidelity could find an intervention to be effective due to extra treatment factors, potentially resulting in an ineffective intervention being found to be significant in an intervention and subsequently implemented in clinical practice (Moncher and Prinz 1991, Resnick et al. 2005a, Hengeller et al. 1997). Finally, fidelity monitoring can aid researchers in moving forward and refining interventions as it provides information on what components of the intervention were effective. [2S]

Treatment fidelity is of particular relevance to behavioural change interventions due to the complexity involved in targeting specific health behaviours, for example PA (Bellg et al. 2004, Michie et al. 2015, Radziewicz et al. 2009). Due to the inherent nature of these complex interventions, there is greater capacity for variation especially when different research sites and treatment providers are involved. [3S] A review of behavioural change interventions between 1990-2000 found that 54% of studies did not report on intervention fidelity (Borrelli et al. 2005). In an effort to rectify this Bellg et al. (2004) as part of the NIH BCC identified five comprehensive domains under which treatment fidelity can be assessed and monitored or enhanced (Table 5.1): (1) design of study, (2)

training providers (3) delivery of treatment (4) reciept of treatment (5) enactment of treatment skills.

In the last decade, since the publication of NIH BCC recommendations on treatment fidelity, some studies have used these recommendations and it appears to be a useful model for monitoring and enhancing treatment fidelity (Robb et al. 2011, Radziewicz et al. 2009, Resnick et al. 2005b) .[2S,15S,16S,27S,343,54S,65S]

Many aspects of physiotherapy include complex interventions (behavioural change, PAIs and exercise interventions). In order to ensure optimal translation of research findings into physiotherapy practice, knowledge of the fidelity of the trials that provide the underpinning evidence is important.

5.1.1 Aim

Therefore, the aim of this chapter was to identify how fidelity is defined in the literature, and to explore the extent to which reported fidelity is assessed/monitored in the published evidence on behaviour change, physiotherapy, physical activity interventions and exercise therapy and how the methods employed in this literature map to the five domains of the NIH BCC.

5.1.2 Objectives

(i) To summarise the definitions of fidelity used in the literature;

(ii) To explore the strategies for assessing and monitoring treatment fidelity and to map how these match the domains of fidelity as described by the NIH BCC (Bellg et al. 2004).

5.2 Methods

The methods involved a scoping review and included a six step framework: (1) identifying the research question; (2) searching for relevant studies; (3) selecting studies; (4) charting the data; (5) collating and summarising our result; (6) Consulting with key stakeholders (not applicable to this study) (Levac et al. 2010, Arksey and O'Malley 2005).

5.2.1 Identifying the research question: The research question which informed this review was "what methods are reported (in literature relating to behaviour change interventions, physical activity, exercise, physiotherapy) to assess/monitor treatment fidelity?"

5.2.2 Searching for relevant studies: A specialised search strategy was developed in consultation with the librarian for the School of Health Sciences, Ulster University. Two reviewers (OO'S, RMcC) independently and systematically searched three key databases (Scopus, Medline (Ovid), and CINAHL). Search words included "fidelity" OR "treatment fidelity" AND "behavio* change;" AND "physiotherapy" OR "physical therapy;" AND "exercise therapy;" AND "physical activity interventions." Searches were restricted to those conducted in humans and published in the English language. The literature was probed in preparation for this review and as a large volume of literature was available it was decided in advance of the search to limit the inclusion criteria to studies published from 2012-2015.

5.2.3 Selecting studies*:* Titles and abstracts were screened independently to identify relevant studies where "fidelity" was used in the context of our review aims. Search results were combined and duplicates removed. Only studies that included a clear method of assessing fidelity were included for data extraction. Review articles, case studies and commentaries were excluded, but held for discussion purposes. Full paper copies were retrieved and divided between the two reviewers; for training and standardisation, five articles selected at random were exchanged between reviewers and reviewed to assess agreement about whether studies met the inclusion criteria.

5.2.4 Charting the data: The research team met regularly to agree and refine the data extraction table. Ultimately the aims and objectives of the papers, a definition or summary of fidelity (if present) and the methods used to assess/measure fidelity were extracted and tabulated by each reviewer. The characteristics (design, population and number of participants) of the studies were also charted.

5.2.5 Collating and summarising our results: The extracted methods used to assess/measure fidelity were summarised and then mapped to the five domains as set out by NIH BCC framework: design of study, training providers, delivery of intervention, receipt of the intervention and enactment of intervention skills (Bellg et al. 2004). At the end of this process the reviewers met to agree the classifications and finalise the data extraction table.

5.3 Results

5.3.1 Literature search results

There were 65 papers included in this scoping review. The search results are available in Figure 5.1. One hundred and thirty seven full text articles were retrieved; 65 of these were included and the remaining 72 papers were excluded for the following reasons: 31 did not report a clear method of how fidelity was monitored or assessed and therefore did not meet the inclusion criteria. A further n=34 were review papers, 5 were editorial/commentaries, 1 was an opinion piece and the remaining 1 was a cross sectional questionnaire study.

The results of the data extraction are summarised in Table 5.3. Further details of the characteristics of the included papers, the definitions of fidelity and methods used to assess/monitor fidelity can be found in the Appendices (Appendix 21, Characteristics and references for included papers in the fidelity review: a scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions). From the large number of studies included in this a review, a broad range of interventions were tested in diverse populations: N= 8 involved healthcare practitioners clinicians and care givers[6S,8S,20S,26S,27S,30S,32S,65S],, n=7 involved children and adolescents [1S,28S,31S,36S,41S,45S,65S], n=6 invovled patients at risk and with diabetes[15S,17S,22S,37S,38S,54S,] n=5 condcuted interventions involving families [7S,23S,33S,55S,60S,] n=4 conducted an intervention with adults with intellectual disabilities[29S,35S47S,49S], n=4 patients with musculoskeletal disorders[13S,19S,40S,48S], n=3 children with autism spectrum disorder[4S,44S,51S], n=3 stroke patients[3S,25S,43S], n=3 alcohol and drug abuse[53S,59S,64S], n=3 smokers[24S,39S,58S,] n=2 cancer patients and cancer survivors[16S,28S,] n=2 specific occupations (school teachers and office workers)[9S,12S], n=2 patients with sleep disorders[21S,62S], n=2 people at risk of developing an illness[50S,56S], n=2 patients with chronic conditions [14S,34S] and n=9 other; including Australian football players [5S], shops that serve latino customers[18S], post menopausal women[46S], people with glaucoma[52S], community dwelling older adults[10S], patients without established cardiovascular disease taking antihypertensive or lipid lowering therapy[11S], obese pregnant women[42S], older adults who have suffered a disabling medical event[57S] and men who have sex with men[61S].

5.3.2 Fidelity definition

Thirty four of the 65 (52.3%) papers gave a definition/short summary of fidelity and of these 23 indicated a reference source for their definition, 21 different authors were referenced for definitions. The definition proposed by Bellg et al. (2004) was the most commonly cited definition of fidelity, cited by 9 of the included papers. Most of the definitions centered around delivering the intervention as planned; 20 [6S,8S-9S,12S,17S-19S,21S-22S,24S,27S-28,S30S,36S,38S-39S,47S,56S,59S,60S] explicity used "delivery" in their definition while a further eight used similar language for example "followed as planned,"implemented as planned" "provided as intended."[5S,16S,23S,31S,35S,42S,57S,65S] Other definitions stated that fidelity is an important component of "verifying a cause-effect relationship within complex interventions,"[7S] and Hildebrand et al. (2012) included treatment differentiation in their definition.[57S]

5.3.3 Strategies for assessing/monitoring treatment fidelity mapped to the NIH BCC domains

Of the 65 papers included in this review only 2/65 (3%) included an assessment of all five domains; 39/65 (60%) papers assessed fidelity under one domain, 12/65 (18.5%) included two domains, 9/65 (13.9%) papers assessed fidelity under three of the NIH BCC domains, and 3/65 (4.6%) addressed four of the five domains.

5.3.3.1 Study Design

Nine studies considered study design in their assessment/monitoring of fidelity (Table 5.3). Four of these studies reported on the underpinning theory.[2S,3S,54S,65S] Seven papers included a prior information on the dose to be delivered, ensuring it was the same between conditions.[11S,15S-16S,30S,34S54S,61S] Two of the included studies trained more than one provider as a strategy to allow for any setbacks.[2S,15S] Beck et al. used a specifc study design to minimise contamination and all providers in this study remained blind to the intervention content during the control period. [2S] Further strategies used to enhance fidelity relating to the domain of study design were incorporated by Winnet et al. (2015), where by they ensured that they would have sufficient statistical power to detect treatment effects. [15S]

5.3.3.2 Training of providers

Twenty two papers reported on the training of intervention providers in their assessment of fidelity (Table 5.3). Strategies reported to enhance provider training included standardisation of training so as all providers received a similar number of sessions or were given standard training manuals. [2S,15S,22S,34S,46S,61S,65S] Role play or practice delivering the intervention was part of the training in nine studies[2S,14S,22S,44S,46S,52S,54S,64S-65S]; provider competence and adherence to the intervention components were usually assessed during these sessions. In efforts to minimise drift, refresher training was provided by Winnett et al. (2015) and others supervised or reviewed audio/video of sessions throughout the intervention and gave the providers feedback based on this; [15S] in one case the sessions were evaluated and if provders scored below a certain level of fidelity they were given additional training. [44S] Other strategies used included: seeking feedback on the training from the providers, [15S] using the results of the assessment of delivery to inform future training [17S] and the trainer reported if they had delivered the training as intended. [33S]

5.3.3.3 Delivery of treatment

Fifty nine papers reviewed included an assessment of delivery (Table 5.3). Thirty nine studies assessed delivery of the intervention either by direct observation or through an evaluation of an audio or visual recording[1S-2S,6S-8S,10S,13S,17S,19S,20S,22S,-28S,32S-36S,39S-41S,44S-47S,51S,55S-58S,61S-65S] The number of actual treatment sessions assessed ranged from 10-100%. The criteria used to evaluate treatment delivery varied and included both objective checklists and subjective measures to evaluate the delivery of the intervention. For example in one study the raters reported on their "overall impression" of how the intervention was delivered[40S] another report evaluated the provider's engagement with the participants and whether the session was delivered in "a constructive and empowering manor."[56S] Other strategies used in the assessment of delivery included an effort to assess/measure the dose delivered (n=8).[8S,12S,23S,25S,31S,38S,42S,59S] The use of materials such as manuals used to enhance or aid delivery was used by four reviewed papers.[10S,15S,16S,62S]

5.3.3.4 Receipt of treatment

Thirteen of the papers included in this review reported an assessment of receipt (Table 5.3). Strategies use to assess receipt varied between authors and included ensuring that participants had an understanding of the intervention[15S, 11S,21S,60S]. Two authors made resources available to the participant so as they could perform the intervention activities. Other strategies included using online tracking codes to assess if participants accessed and received the material; [60S] one protocol reported that receipt would be assessed through brief questionnaires [27S] and Robbins et al. reported that receipt was assessed via providers' logs and assessment of audio recordings. [65S]

5.3.3.5 Enactment of treatment skills

An assessment of enactment of treatment skills was included by 10 of the studies (Table 5.3). The performance of the intervention skills was observed in the real life setting by one study[5S]; similarly two other reports used direct observation to examine the degree to which interventional changes took place. [18S,53S] Faulkner et al. (2012) used an objective measurement to assess if the treatment was being enacted in real life settings. [54S] Follow up contact to assess the enactment of the treatment skills was reported by two studies. [21S,30S]

5.4 Discussion

This review identified the definitions used for treatment fidelity and explored the extent to which the five domains of treatment fidelity are reported in the literature, and detailed the strategies used to capture these five domains. The definition by Bellg et al. (2004) was the most commonly cited definition for treatment fidelity. Most of the definitions provided centred around delivery of the intervention. The overall reporting of treatment fidelity is poor; only 40% reported on more than two of the five components. Treatment delivery was the most frequently reported domain which is consistent with previous research (Borrelli 2011). Study design was the most under reported domain of fidelity with only nine studies including this domain in their analysis. There was a wide variation in the strategies used to assess/monitor fidelity across all domains.

The definition by Bellg et al. (2004) was the most commonly cited definition of treatment fidelity in the reviewed articles. This definition centres mainly around reliability and validity, referring to both the strategies used to monitor and enhance these and the practices to ensure that the research reliably and validly tests the intervention. All of the reasons outlining the importance of measuring treatment fidelity as detailed in the introduction are directly realated to reliablity and validity (both internal and external) and it is likely that this definition provided by Bellg et al. (2004) was developed bearing in mind the benefits of ensuring good treatment fidelity. Borrelli et al. (2005) also draws on upon this definition and was cited by two reviewed studies.[2S,6S] However many of the papers in this review simply deduced fidelity down to the delivery; ensuring an intervention was delivered as intended. This simplified definition and concept of treatment fidelity may have influenced the methods used to assess treatment fidelity. This is evidenced through the results as treatment delivery was the most frequently assessed domain. The definition developed by Bellg et al. (2004) was developed by an expert group and we would encourage the use of this definition to aid in the standardisation of the assessment of treatment fidelity.

As treatment delivery was the most frequently reported domain it appears that authors have a good awareness of the importance of this. However all five components of fidelity are mutually exclusive; lack of consideration to any one category could potentially compromise the validity of the study (Borrelli et al. 2005). For example if an intervention is found to be ineffective and the only domain of fidelity assessed was delivery which was high, it is possible that neglect of other domains may have caused the insignificant results; the providers may not have been adequately trained or the study design may not have tested the hypothesis. There is some debate around the importance and relevance of all five domains. This review found enactment to be comparatively less well reported than the other four domains. Gearing et al. (2011) have conceptualised a treatment fidelity framework that does not include enactment as a core component of fidelity. Gearing et al. (2011) also argue that enactment is a component of treatment efficacy rather than treatment fidelity; participants in a study may remain unwilling or unable to apply the treatment skills in real life settings despite the provider delivering the intervention as per protocol. This is of particular importance to behavioural change interventions. The ultimate goal of behavioural change interventions is to change the participant's behaviour to enable them to engage with or carry out the treatment skills; if the participant remains

unwilling to do so despite full consideration to the other four domains, perhaps this could then indicate that the treatment was ineffective. [2S] However, further work is required to wholly explore and agree this issue and come to a definitive conclusion on the relative importance of each of these five domains.

Study design was the most under reported component of fidelity and may have been over looked as an element of fidelity. Study design is an integral part of any intervention and impacts greatly on the ability of the intervention to evaluate the hypothesis (Bellg et al.2004). Only a small number of the studies in this review included a measure or assessment of study design when reporting fidelity. Bellg et al. (2004) outline specific criteria around study design so that the study can adequately test its hypothesis in relation to its underlying theory. The theory which underpins interventions for behaviour change is important when designing an intervention, as it can provide a more in depth understanding of the processes of how the intervention might work (Davis et al. 2014), yet only four papers referred to a theoretical framework when reporting their fidelity assessment. Other reviews in various populations have found the reporting of the use of theories to underpin interventions ranged from 12-72% (Keogh et al. 2015, Painter et al. 2008, Davies et al. 2010, Prestwich et al. 2013, French et al. 2014, Richardson et al. 2014), The aim of this review was to summarise reported methods used to assess and monitor treatment fidelity; the evaluation of the study design was beyond the scope of this review and it is possible that papers reviewed included components of study design elsewhere.

This review focused on reports published since 2012. In 2011 Borrelli, a member of the research group that published the NIH BCC framework in 2004, published a checklist which further developed the NIH BCC framework into a 39 item checklist which was designed to assess the treatment fidelity of a study across all these five domains. Despite the publication of the checklist preceding the publication of all the papers included in this review, it was only used by two of the studies [2S,15S] reviewed to help inform their assessment of treatment fidelity. Both these papers reported a comprehensive fidelity assessment; Beck et al. (2015) [2S] included four out of the five domains and Winnett et al. (2015) [15S] included all five domains. The lack of reporting of treatment fidelity in this review demonstrates the need for the use of a standard process or checklist to be used by authors so that none of the five components are overlooked. This checklist provides

authors with a structured framework for which to monitor and assess all elements and components of treatment fidelity

Established reporting guidelines exist for the reporting and publication of clinical trials (CONSORT and Transparent Reporting of Evaluations with Nonrandomized Designs (TREND)) (Schulz et al. 2010, Des Jarlais et al. 2004) and protocols (Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2013)). None of these guidelines provide any specific guidance for the assessment and reporting of treatment fidelity. However, some of the components on these checklists do overlap with the NIH BCC guidelines, for example intervention content and dose. More recently Hoffman et al. 2014 published the TIDieR checklist with the aim to improve the completeness of reporting and replicability of interventions. This 12-item checklist contains two items of treatment fidelity (11 and 12). These items are ambiguous and limited in their description stating that only if intervention fidelity was assessed it should be described and if assessed the extent to which it was delivered as planned should be reported. It is however encouraging that fidelity is being included in these new guidelines. The monitoring, assessment and reporting of treatment fidelity would greatly benefit from the development of more explicit and compulsory reporting guidelines in line with the NIH BCC guidelines.

The inattention to treatment fidelity reported in this review may be due in part to the additional resources required to assess treatment fidelity. Assessing and monitoring fidelity requires increased time, equipment and personnel. This increased burden may concern researchers and funding agencies; Bellg et al. (2004) argue that not devoting these resources to treatment fidelity may be more costly in the longer term. Including a plan to assess and monitor treatment fidelity in a study can enhance the translation into clinical settings and reduce the likelihood of ambiguous results. Lawton et al.[9S] provide an example of the importance of monitoring treatment fidelity for reliable and valid results; the authors found that a worksite physical activity intervention delivered across five sites was only found to significantly increase physical activity levels in one site where it was delivered with high fidelity.

5.4.1 Limitations

The actual documentation and reporting of fidelity within published papers was a central limitation to this review. This may be due in part to restrictions on word count for journal publication. One way to overcome this issue is to provide online supplements so that the scientific community can access any additional information about the methods for assessing and monitoring treatment fidelity.

Finally the mapping of the reported methods of fidelity to the domains of fidelity as set out by the NIH BCC was based on reviewers' judgement. This may have led to some misclassification of methods; however attempts were made to reduce this as classifications were agreed by the two reviewers and regular meetings were held with a more experienced researcher throughout the process who was consulted when any disparity arouse.

5.5 Conclusion

In this scoping review we identified that there remains an inconsistency and paucity across the literature for the defining and reporting of methods for treatment fidelity assessment and monitoring in complex interventions. We recommned that future researchers should use the definition proposed by Bellg et al. (2004) A fidelity framework such as that published by Borrelli (2011) will support the comprehensive consideration and reporting of treatment fidelity in future research activities. The use of this checklist to embed fidelity into clinical trials will ultimately enhance the translation of research into practice.

Figures

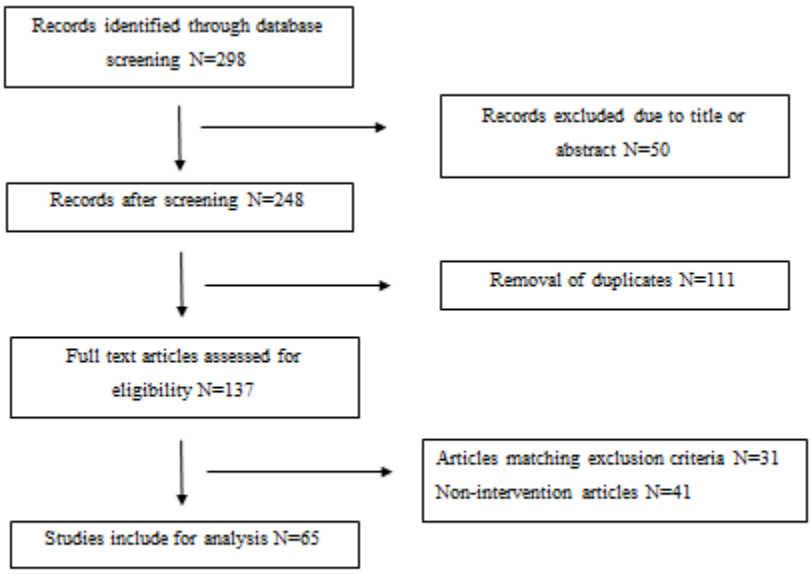

Figure 5-1 Summary of literature review search records using PRISMA group flow chart

Tables

Table 5-2 NIH BCC Domains of Treatment Fidelity. Bellg et al. 2004

Design of study: Treatment fidelity practices related to study design ensure that a study adequately tests its hypotheses in relation to its underlying theoretical and clinical processes. *Training providers*: Treatment fidelity involves assessing and improving the training of treatment providers to ensure that they have been satisfactorily trained to deliver the intervention to study participants. *Delivery of treatment:* Treatment fidelity processes that monitor and improve delivery of the intervention so that it is delivered as intended *Receipt of treatment:* Receipt of treatment involves processes that monitor and improve the ability of patients to understand and perform treatment-related behavioural skills and cognitive strategies during treatment delivery. *Enactment of treatment skills:* Enactment of treatment skills consists of processes to monitor and improve the ability of patients to perform treatment-related behavioural skills and cognitive strategies in relevant real-life settings. *Definition:* Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions. It also refers to the methodological practices used to ensure that a research study reliably and validly tests a clinical intervention.

Table 5-3 Summary of results from scoping review

Reference*	Definition	1	2	3	4	5	Number of components
Bailey et al. 2015[1S]	No definition			✓			1/5
Beck et al. 2015[2S]	Yes (Borrelli et al. 2005)	✓	✓	✓	✓		4/5
Casey et al. 2015[3S]	No definition			✓			1/5
Chesworth et al. 2015[4S]	Yes (Bellg et al. 2004)			✓			1/5:
Fortington et al. 2014[5S]	Yes (Hansen 2013, Allen et al. 2012)					✓	1/5
French et al. 2015[6S]	Yes (Bellg et al. 2004, Borrelli et al. 2005)			✓			1/5
Fulkerson et al. 2015[7S]	No definition			✓			1/5
Hanbury et al. 2015[8S]	Yes (no reference)			✓			1/5
Lawton et al. 2015[9S]	Yes (Bellg et al. 2004, Oakley et al. 2006, Craig et al. 2008)			✓	✓	✓	3/5
Martin et al. 2015[10S]	No definition			✓			1/5
McNamara et al. 2015[11S]	Yes (Craig et al. 2008)	✓		✓	✓		3/5
Pawar et al. 2015[12S]	No definition			✓			1/5
Pincus et al. 2015[13S]	No definition						1/5
Williams et al. 2015[14S]	No definition		✓				1/5
Winnett et al. 2015[15S]	No definition	✓	✓	✓	✓	✓	5/5
Wyatt et al. 2015[16S]	Yes (Radziewicz et al. 2009, Calsyn 2000, Wyatt 2010)	✓	✓	✓	✓		4/5
Avery et al. 2014[17S]	Yes (Resnick et al. 2005a)		✓	✓			2/5
Baquero et al. 2014[18S]	Yes (no reference)		✓	✓		✓	3/5
Bryant et al. 2014[19S]	Yes (Bellg et al. 2004)		✓	✓			2/5

Dewing et al. 2014[20S]	No definition			✓			1/5
Dyas et al. 2014[21S]	Yes (Bruckenthal and Broderick 2009)			✓	✓	✓	3/5
Hardeman et al. 2014[22S]	Yes (Bellg et al. 2004)		✓	✓			2/5
Kulwa et al. 2014[23S]	Yes (no reference)		✓	✓			2/5
Lorencatto et al. 2014[24S]	Yes (Borrelli 2011)			✓			1/5
McKenzie et al. 2014[25S]	No definition			✓			1/5
Neilson et al. 2014[26S]	No definition		✓	✓			2/5
Presseau et al. 2014[27S]	Yes (no reference)			✓	✓	✓	3/5
Robbins et al. 2014[28S]	Yes (Linnan and Steckler 2002)			✓			1/5
Van Schijindel-Speet et al. 2014[29S]	Yes (Baranowski et al. 2000, Saunders et al. 2005, Glasgow 2006)			✓			1/5
Washington et al. 2014[30S]	Yes (Glasgow et al. 1999)	✓			✓	✓	3/5
Almas et al. 2013[31S]	Yes (no reference)			✓			1/5
Bach et al. 2013[32S]	No definition			✓			1/5
Barber et al. 2013[33S]	No definition		✓	✓			2/5
Benzo et al. 2013[34S]	No definition	✓	✓	✓			3/5
Bergstrom et al. 2013[35S]	Yes (Fraser 2009)			✓			1/5
Branscum et al. 2013[36S]	Yes (no reference).			✓			1/5
Gabbay et al. 2013[37S]	No definition		✓	✓			2/5
Goode et al. 2013[38S]	Yes (Fraser 2009)			✓	✓		2/5
Lorencatto et al. 2013[39S]	Yes (Bellg et al. 2004, Borrelli 2011)			✓			1/5
Mars et al. 2013[40S]	Yes (Bellg et al. 2004)			✓			1/5

Pfeiffer et al. 2013[41S]	No definition			✓			1/5
Poston et al. 2013[42S]	Yes (no reference)			✓			1/5
Scobbie et al. 2013[43S]	No definition/			✓			1/5
Sears et al. 2013[44S]	No definition		✓	✓			2/5
Seo et al. 2013[45S]	No definition			✓			1/5
Sternfield et al. 2013[46S]	No definition		✓	✓			2/5
Wilner et al. 2013[47S]	Yes (Moncher and Prinz 1991)			✓			1/4
Zheng et al. 2013[48S]	No definition			✓			1/5
Bodde et al. 2012[49S]	No definition			✓			1/5
Broekhuizen et al. 2012[50S]	No definition			✓			1/5
Brookman-Frazee et al. 2012[51S]	No definition			✓			1/5
Cate et al. 2012[52S]	No definition		✓				1/5
Cowan and Devine 2012[53S]	No definition					✓	1/5
Faulkner et al. 2012[54S]	Yes (Bellg et al. 2004)	✓	✓	✓	✓	✓	5/5
Gallanter et al. 2012[55S]	No definition			✓			1/5
Heideman et al. 2012[56S]	Yes (no reference)			✓			1/5
Hildebrand et al. 2012[57S]	Yes (Perepletchikova and Kazdin 2005, Sharpless and Barber 2009)			✓			1/5
Hollands et al. 2012[58S]	No definition			✓			1/5
Irvine et al. 2012[59S]	Yes (no reference).			✓			1/5
Knowlden and Sharma 2012[60S]	Yes (no reference)				✓		1/5
Llewellyn et al. 2012[61S]	Yes (no reference).	✓	✓	✓			3/5
McCurry et al. 2012[62S]	No definition			✓	✓	✓	3/5

Moore et al. 2012[63S]	No definition		✓	✓			2/5
Morganstrern et Al. 2012[64S]	No definition		✓	✓			2/5
Robbins et al. 2012[65S]	Yes (Bellg et al. 2004)	✓	✓	✓	✓	✓	4/5

*Reference list included in Appendix 20
1=Study design
2= Training of providers
3=Delivery of treatment
4= Receipt of treatment
5= Enactment of treatment

Chapter 6 - Assessment of the Fidelity of the LIVELY PAI

6.0 Chapter overview

This chapter describes the methods used to assess the treatment fidelity and the results of the assessment of treatment fidelity of the LIVELY PAI (Chapter 3), utilising the Borrelii 2011 checklist as a framework. The researchers who were involved in conducting this research and their roles are detailed in Table 6.1.

Table 6-1 Role of members of study team

Person	Role
Orlagh O'Shea	-Development of fidelity assessment protocol -Mapping of Borrelli (2011) checklist to the LIVELY intervention -Development of LIVELY specific checklists - Assessment of practicality and acceptability of LIVELY specific checklists -Fidelity assessment (primary rater) -Analysis and write up
Dr Brenda O'Neill	-Training of providers -Development of fidelity assessment protocol -Mapping of Borrelli (2011) checklist to the LIVELY intervention -Development of checklists LIVELY specific -Assessment of practicality and acceptability of LIVELY specific checklists -Fidelity assessment (secondary rater) - Intellectual contribution to interpretation of results and write up of chapter
Professor Judy Bradley	-Training of providers -Development of fidelity assessment protocol -Provided mentorship to the providers throughout the intervention -Mapping of Borrelli (2011) checklist to the LIVELY intervention - Development of LIVELY specific checklists -Assessment of practicality and acceptability of LIVELY specific

	checklists -Fidelity assessment (secondary rater) - Intellectual contribution to interpretation of results and write up of chapter
Professor Suzanne McDonough	-Training of providers -Development of fidelity assessment protocol -Provided mentorship to the providers throughout the intervention -Assessment of practicality and acceptability of LIVELY specific checklists -Fidelity assessment (secondary rater) - Intellectual contribution to interpretation of results and write up of chapter
Professor Madelynne Arden	-Development of fidelity assessment protocol -Assessment of practicality and acceptability of LIVELY specific checklists -Fidelity assessment (main secondary rater). - Intellectual contribution to interpretation of results

6.1 Introduction

There is no agreed definition for treatment fidelity (O'Shea et al. 2016). However treatment fidelity is frequently defined as the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions; it also includes the methodological practices used to ensure that a research study reliably and validly tests a clinical intervention (Bellg et al. 2004). The assessment and monitoring of treatment fidelity has been identified as an important and valuable process in research to ensure that an intervention is delivered as intended. Knowledge of how the intervention was delivered can also help to refine an intervention, and may aid the translation of interventions into clinical practice (Bellg et al 2004). Additionally the MRC guidelines have recommended evaluating treatment fidelity in complex interventions (Craig et al. 2008). The LIVELY COPD PAI is a complex behaviour change intervention with the potential to be delivered in clinical practice. Furthermore the LIVELY PAI is part of the randomised controlled feasibility study in this thesis and has the capacity to be further tested in a future larger RCT. Assessing the treatment fidelity of the LIVELY PAI was

therefore identified as key aim of the LIVELY COPD project. If fidelity is not monitored the results cannot be fully supported as it is possible that additional unplanned components were delivered without the researchers knowledge (Moncher and Prinz 1991). In addition to this the implementation of an intervention across multiple sites by multiple providers can increase the capacity for variation; the LIVELY PAI was delivered across six different sites by three different intervention providers.

Treatment fidelity is a concept that often is neglected in the literature in general (Borrelli et al 2005, Dusenbury 2003, O'Shea et al. 2016) and in physiotherapy interventions specifically (Huijg et al. 2015, Toomey et al. 2014). Methods to assess and monitor the treatment fidelity of a complex intervention are also limited (O'Donnell 2008). For guidance on how the treatment fidelity of a PAI in the COPD population could be assessed we explored the literature on PAIs in COPD. Twenty papers that had been included in a recent review on PAIs in COPD by Wilson et al. 2014, were assessed using the TIDieR checklist. The TIDieR checklist is a 12 item checklist that was designed to "*improve the completeness of reporting and ultimately the replicability of interventions."* This checklist contains two items (11 and 12) that specifically relate to the reporting of the fidelity of an intervention, (item 11: If intervention adherence of fidelity was assessed describe how and by whom, and if any strategies were used to maintain or improve fidelity describe them and item 12: If intervention adherence or fidelity was assessed, describe the extent to which it was delivered as planned). Few studies in this review (n=3/20) met these criteria (Berry et al. 2010, Berry et al. 2003 and Tabak et al. 2014) (Appendix 22, summary table of results of assessment of studies included in a systematic review by Wilson et al. 2014 with the TIDieR checklist). These three papers only reported the following information in relation to fidelity; Berry et al. 2003 and Berry et al 2010 explored participant compliance (the number of session completed versus the number of planned sessions) and Tabak et al. (2014) reported on a telehealth intervention and assessed the number of sessions participants logged onto the web portal to complete. None of these papers provided a procedure or framework for the assessment of fidelity that could be replicated, or provided guidance on how treatment fidelity could be assessed within the LIVELY PAI.

Therefore with no available guidance from the COPD literature, a review was undertaken to identify the most common methods used to monitor fidelity in the wider literature. A

detailed report and the results of this review can be found elsewhere (Chapter 5). The conclusion of this review was that the checklist published by Borrelli 2011 could be used to support the assessment and reporting of treatment fidelity in future research (Appendix 23, Blank Borrelli 2011 checklist). The Borrelli (2011) checklist was based on the best practice guidelines and recommendations published by the NIH BCC (Bellg et al. 2004). These guidelines outline five key domains for treatment fidelity (Chapter 5, Table 5.2), which have been used to inform the assessment, monitoring and enhancement of fidelity in a number of trials (Beck et al. 2015, Winnet et al. 2015, Wyatt et al. 2015, Presseau et al. 2014, Benzo et al 2013, Faulkner et al. 2012. Robbins et al. 2012, Robb et al. 2011, Radziewicz et al. 2009, Resnick et al. 2005b). The Borrelli (2011) checklist has further been used to assess the reporting of treatment fidelity in physiotherapy interventions to promote self-management of osteoarthritis and chronic low back pain (Toomey et al. 2014). To the best of our knowledge the Borrelli (2011) checklist has never been used as a framework to assess the fidelity of an intervention.

6.1.1 Aim

The aim of this chapter therefore, was to assess the fidelity of the LIVELY PAI.

6.1.2 Objectives

(i) To develop a protocol to assess the fidelity of the LIVELY PAI using the Borelli (2011) checklist as a framework.

(ii) To test the acceptability and practicality of tools developed within the protocol to assess different domains of treatment fidelity in the LIVELY intervention.

(iii) To complete the fidelity assessment across all five domains (Chapter 5, Table 5.2).

6.2 Methods

The LIVELY intervention took place between April 2014 and January 2016. The fidelity assessment of the LIVELY intervention commenced in October 2014 and was completed in July 2016. A flow diagram of the methods can be found in Figure 6.1.

Step 1 Mapping the Borrelli (2011) checklist to the LIVELY intervention including developing assessment tools specific for the LIVELY intervention

During this step each item on the Borrelli (2011) checklist was considered in the context of the LIVELY COPD project as well as how the assessment could be satisfied or achieved. Some specific assessment tools and checklists were developed.

1. **Study design:** The LIVELY study documents were to be reviewed to assess if the 6 items on the Borrelli checklist were satisfied or how they could be further satisfied in the context of the LIVELY COPD project. The LIVELY study documents refer to the full study protocol, the grant application, the PAI file and minutes of all study meetings. A plan was also set out to assess the treatment dose of PR (the comparison condition) at each site (Appendix 24, Pulmonary Rehabilitation check form for all sites included in the LIVELY COPD project). The methods for mapping the study design items to the LIVELY project are available in Table 6.2.
2. **Training of providers:** A specific training procedure and materials were designed for the LIVELY study. These training materials, in addition to the study documents were to be reviewed to assess if items on the Borrelli (2011) checklist were satisfied in the context of the LIVELY study. Where the protocol could not provide enough detail to fulfill the criteria for an item on the checklist, additional resources or tools were developed. For example a questionniare to assess whether the participants felt the training plan took into account their different education, experience and learning styles was developed (Appendix 25, Evaluation of training of providers for the delivery of the LIVELY PAI- provider feedback evaluation questionnaire); intervention providers were mentored throughout the programme as part of training and a report on how this mentorship took place was obtained from the mentors. The mapping of all items under training of providers for the LIVELY COPD project is included in Table 6.3.
3. **Delivery of treatment:** "*The gold standard to ensure satisfactory delivery is to evaluate or code intervention sessions (observed in vivo or video- or audiotaped) according to a priori criteria* (Bellg et al. 2004)*."* It was planned to audio record all consultations (i.e.1-12) with two participants from each of the 3 providers. The

a priori criteria were in accordance with the BCSs that were specifically considered in the LIVELY PAI (Appendix 26, List of original Behaviour Change Strategies for the LIVELY PAI, on CD-ROM) as well as the consultation schedule for each consultation. The BCSs were mapped specifically to the consultation they were planned to be delivered in and checklists were made for each consultation to record the assessment of delivery. The consultation schedule was found at the start of each consultation plan and this informed the layout of the template for providers to record their consultation notes. The delivery checklists contained check boxes to record if a component was delivered and space to document notes. The components to be delivered throughout consultation 3-11 (with the exception of consultation 5) were the same; a single checklist was created for these and additional delivery checklist created for consultations 1,2,5 and 12 (Appendix 27, Original delivery checklists developed specifically for the assessment of fidelity of the LIVELY PAI, on CD-ROM). The audio recordings and intervention provider notes of consultations were to be used to assess delivery. Table 6.4 summarises the method for mapping of items under delivery treatment to the LIVELY PAI.

4. **Receipt of treatment**: There are 5 distinct items in the Borrelli checklist on receipt. To assess how these items could be fulfilled the LIVELY study documents were reviewed (Table 6.5). Elements of the LIVELY study protocol that matched these criteria were mapped to the consultations they were planned to be received in by the participant, and a single checklist was developed (Appendix 28, Original receipt checklist developed specifically for the assessment of fidelity of the LIVLEY PAI, on CD-ROM) to enable the full assessment of receipt. To formally assess receipt; the audio recordings and intervention provider consultation notes were to be reviewed with the receipt checklist.
5. **Enactment of treatment:** There are two items under enactment on the Borrelli (2011) checklist. The LIVELY study documents were reviewed to plan how enactment was to be assessed throughout the LIVELY PAI. An enactment checklist was developed to enable the full assessment of this domain (Appendix 29, Original enactment checklist developed specifically for the assessment of fidelity of the LIVELY PAI, on CD-ROM) (Table 6.6). Enactment was to be assessed by reviewing the audio recordings and provider consultation notes against the checklist.

Step 2: Testing the practicality and acceptability of the assessment tools for delivery, receipt and enactment with the research team

In this part of our methods we explored the practicality and acceptability of the checklists developed in step 1 to assess delivery, receipt and enactment. Audio recordings and consultation notes for one patient (C124) were chosen randomly to assess the practicality and acceptability of the delivery, receipt and enactment checklists that had been developed specifically for the LIVLEY PAI. All members of the team were involved in this stage. All checklists were assessed by at least two researchers to assess consistency. The consultations were divided among the team pragmatically: SMcD: consultation 1 and 2, BO'N: consultation 5 and 7, JB: consultations 6 and 12, and MA: consultations 5 and 12; and the primary researcher OO'S assessed all consultations. Each member was given access to the audio recordings and provider notes (all of which were anonymised for this patient).

The team met in January 2016 to discuss how the checklists developed during step 1 worked in practice. A number of amendments were made to the checklists following recommendations from this meeting for example, changes to the layout and wording were made to promote clarity such as "action plan and barriers discussed," was amended split into "Action and coping plan completed," and "barriers discussed.". The amended checklists were reviewed and finalised by the team. All updated checklists can be found in the Appendices 30-32 (Appendix 30, Amended delivery checklist developed specifically for the assessment of fidelity of the LIVELY PAI, Appendix 31, Amended Receipt checklist developed specifically for the assessment of fidelity of the LIVELY PAI, Appendix 32, Amended enactment checklist developed specifically for the assessment of fidelity of the LIVELY PAI).

Step 3: Completing the assessment of the LIVELY intervention

1. **Study design**: The Borelli (2011) checklist was populated with information obtained from the LIVELY study documents and the self-check questionnaire was completed by all PR sites The PR self-check was conducted in February 2015.
2. **Training of providers:** The Borelli (2011) checklist was populated with information obtained from the LIVELY study documents. The questionnaire to

assess if the providers felt the training took into account their individual training needs, education and learning styles was circulated in February 2015 prior to training day five. The mentors (JB and SMcD) provided the report on mentorship in June 2016.

3. **Delivery of treatment**: The Borelli (2011) checklist was populated with information obtained from the LIVELY study documents. Based on the availability of recordings we adopted a pragmatic approach and assessed delivery by each provider across the entire intervention to one participant (i.e. consultations 1-12 from each provider to a single participant). These were chosen based upon the most complete set of recordings by provider for a single patient. We therefore assessed 16.3% (n=36/221) of all consultations.

   Each consultation was assessed by two members of the team; OO'S as the primary rater and one other (secondary rater (MA)). Details can be found in Table 6.7. The primary rater and secondary rater assessed the consultations separately and then met to discuss their findings. If any disparities arose the rater notes and audio recordings were revisited for supporting evidence.

   To summarise the findings of delivery, fidelity was defined as the number times a component was delivered by each provider compared to the planned protocol. These were then expressed as a percentage and a mean overall value for each component was obtained. There was a discussion among the research team of what percentage of components on the delivery checklists should be adhered to; an "a priori specification of treatment fidelity." It was decided that in line with current recommendations (Borrelli et al. 2005) providers should adhere to greater than 80% to be considered high treatment fidelity.
4. **Receipt of treatment:** Receipt was assessed by the research team as outlined in Table 6.7. The findings of the assessment between the primary and secondary rater(s) were discussed and if any disparities arouse the audio recordings or provider notes were revisited for supporting evidence. It was then recorded how many times a component was actually received versus how many times it was planned from each participant; these values were expressed as a percentage and mean overall value for each component was then obtained.

5. **Enactment of treatment:** For the assessment of enactment the consultations were assessed by the team as detailed in Table 6.7. The primary and secondary rater(s) then discussed their findings and any differences were further explored by reviewing the audio recordings or provider notes. The number of times a component enacted by each participant was recorded and expressed as a percentage of the number of times it was planned to be enacted.

6.3 Results

Results of testing acceptability and practicality of delivery, receipt and enactment checklists

The checklists were amended as a result of testing the acceptability and practicality of the checklist. The list of BCSs was also amended under the guidance of health psychologist MA. For example; "Plan coping behaviour using action /coping plan," was removed as it was felt this was already covered under "Plan behaviour using action and coping plan." One item "Reviewing overall SMART goal," was added to the list. The items "Reward self," and "If goals are met increase and reward success," were combined and changed to "Reward success or effort." The updated list of BCSs can be found in (Appendix 6, Amended list of Behaviour Change Strategies included in the LIVELY PAI). Changes to wording or grammar were also made to some checklists increase clarity in for example in checklist 3-11 "action plan and barriers discussed," was changed to (i) "action and coping plan completed," and (ii) "barriers discussed."

Members of the team also had queries regarding the receipt and enactment checklists. For example; "discuss benefits to PA" was an item on both the delivery and receipt checklists. It was clarified that in delivery the emphasis is on the provider, however in relation to receipt the focus is on the participant; to fulfill this criteria, the rater is assessing the patient's involvement in this discussion. Changes were also made to the receipt checklist, for example; "stages of change and additional strategies" was removed as a strategy to improve participant performance of the intervention skills in settings during the intervention period as it was not deemed relevant. Furthermore there was some confusion regarding the differentiation between the two items under enactment on the Borrelli (2011) checklist. The author (Dr. Borrelli) was contacted to seek increased clarity around this. We were provided with three articles (Borrelli et al. 2005, Campbell et al. 2005 and

Borrelli 2011). Based on recommendations from these articles the enactment checklist was revised to better reflect the criteria of enactment.

All the original checklist and amended checklists developed specifically for the assessment of fidelity of the LIVELY PAI can be found in the appendices demonstrating the full extent of changes (Original Checklists on CD-ROM: Appendix 27 Original delivery checklist, Appendix 28 Original receipt checklist, Appendix 29 Original enactment checklist; Amended Checklists: Appendix 30, Amended delivery checklist, Appendix 31 Amended receipt checklist, Appendix 32, Amended enactment checklist).

Results of the assessment of the fidelity of the LIVELY PAI utilising the finalised assessment process and tools.

1. **Study design:** The LIVELY COPD project fulfilled almost all items (5/6) on the Borrelli checklist under study design, as detailed in Table 6.8. As this was a feasibility study potential confounders (item 5) that may have limited our ability to make conclusions at the end of the trial were not identified so this criterion could not be fulfilled. The full results of the PR self-check can be found in the appendices (Appendix 33, Results of the pulmonary rehabilitation check of sites included in the LIVELY COPD project, on CD-ROM).

2. **Training of providers:** The results of the training of providers as per the Borelli (2011) checklist can be found in Table 6.9. All 7 items under this domain were met in the LIVELY COPD project. A description of how the trainers were to be trained was set out from the outset. An examination of the described training plan (Appendix 5, PAI file, section, 9, Training, on CD-ROM) found some minor discrepancies between the planned and actual training of providers. The first 3 sessions were conducted as planned. It was planned to have a training session every 6 months thereafter but the 4th session was conducted 4 months later and the 5th, 6 months thereafter. The final participant completed the study seven months following the training day 5 with no further formal training having been conducted in this period. The actual training conducted reflected the recruitment rates to the LIVELY PAI.

Providers were mentored by experienced members of the LIVELY study team throughout the whole study. Each week there was contact between the mentor and provider before and after each consultation. They discussed the consultation plan prior to the consultation and after the consultation they discussed if any problems arose during the consultation. As a result of this contact process changes were made to the template for intervention provider notes to provide additional guidance for the providers and clarity in their notes. As the intervention progressed this communication took place via email with the option of phone call discussions if necessary. In some cases the weekly contact was reduced due to annual leave.

A feedback evaluation questionnaire to evaluate whether providers felt the training plan that took into account their different education and experience and learning styles was administered to the providers (n=3) prior to training day 4. The evaluation of training was very positive, with all respondents agreeing (n=2) or strongly agreeing (n=1) that the early training was adequate to prepare them to start the intervention and that the on-going training was regular enough. They also agreed (n=2) or strongly agreed (n=1) that the training accounted for their individual learning styles, experience and education. Feedback and suggestions regarding future training (for example the use of real case studies from the LIVELY PAI) was taken into consideration and incorporated into the later training sessions.

3. **Delivery of treatment:** The results of the assessment of delivery of the LIVELY PAI with the Borrelli (2011) checklist can be found in Table 6.10. Eight of the nine items under this domain were met. In some instances the duration of the intervention was either shorter or longer than the planned 12 weeks; mean duration 12.7 (SD:2); range; 9.3-17 weeks. The following item under this domain was not met; “nonspecific treatment effects,” were not considered for the LIVELY PAI. However the remaining eight items were fulfilled, additional procedures had been put in place to fulfill these criteria through the audio taping of consultations and development of checklists.

The devised plan for audio recording consultations was revised during the study due to drop outs and refusal of consent by a participant. Therefore providers were subsequently instructed to record all remaining consultations to ensure there were a sufficient number of audio recordings available to assess delivery of the PAI. There were a total of 221 consultations conducted; 34% (n=75) of these were completed before the fidelity protocol was finalised, a further 16.3% (n=36) were not recorded due to changes to the fidelity protocol, one participant declined to be audio recorded therefore their twelve consultations (5.4%) were not recorded and 8.1% (n=18) were not recorded due to errors (recorder, provider and researcher error). Therefore, 80 consultations (36.2%) were recorded. In total 36 consultations were assessed (16.3%); 14% had an audio recording available to assess the delivery, receipt and enactment of the intervention; the further n=5 (2.3%) consultations were assessed by reviewing the clinician notes only, as recordings were not available due to error. A summary report on all recordings is available in the appendices (Appendix 34, Summary of available recordings of LIVELY PAI consultations).

Nine of the 20 BCSs were delivered 100% of the time. A further n=5 were delivered on >80% of intended occasions. Of the remaining BCSs n=4 were delivered between 50-80% of occasions and n=2 were delivered on <50% of planned occasions, (i.e. the clinician encouraging social support (walking with family or friends or walking to someone) and the certificate of achievement were delivered with the lowest level of fidelity 48.5% and 33.3% respectively). The results of the assessment of delivery of these BCSs are summarised below in Table 6.11. Provider 2 was the least consistent in delivering the BCSs per protocol; delivering eight components with sub optimal fidelity (<80% of the times) compared to four by the other providers.

Nearly all of the components from the consultation schedule were delivered with >80% fidelity and only n=1 component was delivered with <80% fidelity, (i.e. the component “Remind patient of the goal of the programme” was only delivered on 66.6% of planned occasions). These results are summarised in Table 6.12. The delivery of these components was delivered with the lowest fidelity by provider 2 (Table 6.13).

4. **Receipt of treatment:** Receipt is assessed under 5 separate items on the Borrelli (2011) checklist. The population of Borrelli (2011) checklist for the receipt of treatment is available in Table 6.13. The results of the assessment of receipt by item are detailed:
    (1) *"There is an assessment of the degree to which participants understand the intervention":* The familiarisation week assessed the participants' understanding of the intervention to some degree, whereby the participants were given an opportunity to practice recording their daily steps from the pedometer in the step diary. This was received by all participants.
    (2) *"There are specification strategies that will be used to improve participant comprehension of the intervention":* There were nine strategies noted under this item. Seven of these strategies were received on 100% of occasions. The educational component was only received with 83.3% fidelity; one participant received 50% of the education. A recap on the benefits of PA was to be received by patients at consultations 3-11; this was received with 33.3% fidelity. Participant 1 and 2 received it on 22.2% of occasions and participant 3 on 55.5% of occasions.
    (3) *"The participants' ability to perform the intervention skills will be assessed during the intervention process*": All the components under this item were received with 100% fidelity. One method which was used to assess the participants' ability to perform the skills was the use of the pedometer and step diary, the step diaries were not copied to the research team and this could therefore not be assessed. The pedometer was consistently used throughout the intervention and this component was deemed to be received with 100% fidelity.
    (4) "A strategy will be used to improve participant performance of intervention skills during the intervention period": Six strategies were included in the LIVELY PAI under this item. All strategies except for one were received on 100% of occasions; Providers were to help the participants identify strategies from the previous week that enabled them to do more walking so as they can better perform the intervention skills in the coming weeks. This was only received on 90% of occasions for

participant 1 and 40% for participant 2; it was received 100% of occasions for the third participant.

(5) *"Multicultural factors considered in the development and delivery of the intervention":* This item was only relevant to participant 2. These factors were taken into consideration when planning the delivery of the intervention to this individual.

These results are summarised in Table 6.14

5. **Enactment of treatment:** There are two items under enactment on the Borrelli checklist. A summary of how this checklist was populated is available in Table 6.15.

   (1) *Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.* The first week of the intervention was a familiarisation week. Participants were given their pedometer and step diary, only to record their daily steps. There was some mismatch between the step diary and the seven day pedometer recall; this was only enacted on 50% occasions and due to unforeseen circumstances this could not be assessed for one participant as there were five weeks between their first and second consultation. Providers were required to review the extent to which the participant followed their action plan to assess enactment; this was completed on 70% of occasions. Provider 1 assessed this on 90% of occasions and providers 2 and 3 assessed this on 60% of occasions.

   (2) *A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.* All components under this item were enacted with 100% fidelity across the intervention.

   Results of the assessment of enactment from the audio and provider notes are available in Table 6.16.

6.4 Discussion

This chapter describes a working example for assessing the fidelity of a PAI for people with COPD using the Borrelli checklist (2011). The overall aim of this chapter was to assess the fidelity of the LIVELY PAI. This was achieved by firstly mapping the items

on the Borrelli (2011) checklists to the LIVELY PAI, and developing specific checklists and procedures to satisfy these items, secondly testing the acceptability and practicality of these checklists and finally by applying all processes to complete the assessment of fidelity of the LIVELY PAI. The fidelity of the LIVELY PAI was high. However this is a novel piece of research and a number of key lessons were learned during process. Specifically, fidelity should be considered in the design phase of a study to ensure that all aspects can be fully assessed.

The Borrelli (2011) checklist is user friendly, with detailed rationale provided for each item. Further guidance on how to fulfill each item can be found in Bellg et al. 2004. However, we did need to develop further checklists to allow us to determine whether we fully met criteria on the checklists. The assessment of training of providers, delivery, receipt and enactment were more challenging than the assessment of study design as most of the study design detail was included in the protocol. Finally we did require further clarification for the items under the domain of enactment from the author (Borrelli 2011).

Study design is a domain in treatment fidelity that is frequently omitted from fidelity assessment (O'Shea et al. 2016). In the current trial all items under study design in the Borrelli (2011) checklist were examined except for one; "*potential confounders that limit the ability to make conclusions at the end of the trial,*" were not identified. These were not identified as the LIVELY COPD project is a feasibility trial; we did not aim to make conclusions regarding the effectiveness of the intervention and instead aimed to report on the feasibility of this trail. By definition a feasibility study is "a test of the methods and procedures to be used on a larger scale," (Last 2001). Therefore it can be argued that the purpose of a feasibility trial is used to identify potential confounders before progressing to a larger scale trial and "identifying potential confounders that limit the ability to make conclusions at the end of the trial," is not an applicable criterion for feasibility trials.

Borrelli et al. 2005 stated that, inattention to any one of the categories of treatment fidelity could compromise the internal validity of the study despite adherence to the other categories. This is particularly relevant to the training of providers in the current fidelity assessment. All items for the training of providers on the Borrelli (2011) checklist were met. One provider did not attend the first two training sessions due to unforeseen circumstances; while attempts were made to compensate for this through individual

training, the result of this missed training may have impacted on the delivery of the intervention. One provider delivered the BCSs with less fidelity compared to the other two providers; eight of the BCSs were delivered with <80% fidelity compared to four by providers 1 and 3. In addition, the items on the consultation plan were delivered with the lowest level of fidelity by this provider (n=4 delivered with <80% fidelity). Our assessment of delivery was limited to 16.3% of all consultations; stronger conclusions could be drawn regarding this should a greater number of consultations have been assessed.

Overall the assessment of delivery conducted in the current study demonstrated nearly all components of the intervention were delivered with high fidelity (>80%). Components of the intervention comprised of BCSs and the components on the consultation schedule; 70% (n=14/20) of BCSs were delivered with high fidelity and 96.7% (n=29/30) of components on the consultation schedule were delivered with high fidelity. Only two (10%) of the 20 prescribed BCSs were delivered with low fidelity (<50%) (Perepletchikova and Kazdin 2005) and four were delivered with moderate fidelity (50-80%). Researchers have indicated that <50% is low fidelity (Perepletchikova and Kazdin 2005) and >80% is considered high fidelity (Borrelli et al 2005); it is therefore reasonable to consider 50-80% as moderate fidelity. There is lack of consistency in the assessment and reporting of fidelity in the current literature (O'Shea et al. 2016) making it difficult to draw comparisons between our results and others. However French et al. 2015 explored the fidelity of an educational intervention to improve GP management of low back; they reported that only 57% (4/7) BCSs were delivered with high fidelity and no BCSs in this trial were delivered with low fidelity (<50%).

In an attempt to understand why 10% (n=2/20) of BCSs in the LIVELY PAI were delivered with low fidelity, we reviewed the training materials of the LIVELY PAI. Providers in the LIVELY PAI were trained to deliver all BCSs with the exception of "certificate of achievement". This was not included in the training and was only delivered with 33.3% fidelity. Additionally the BCS "Clinician encourages social support, walking with friends/family or walking to meet somebody etc.," was also poorly delivered (48.5%). This BCS was to be delivered in consultations 2-12. Encouraging social support for all participants each week may not have been appropriate for all participants, for example, those who were more isolated or preferred to complete their PA alone. It is

possible the providers delivering the current PAI somewhat tailored the BCSs to each participants needs each week. A recent publication from Procter et al. (2014) reported that if an intervention is employing BCSs, a sufficient number of strategies should be included such that the BCSs in the intervention can be tailored to each participant's needs. A future trial should consider increasing the number of BCSs included to allow for adaption to each individual and potentially increase the fidelity of the intervention.

The domains of receipt and enactment shift the focus from the provider and to the participant. Measuring fidelity in these domains is of particular importance as patients are increasingly regarded as active participants in healthcare rather than passive (Newman et al. 2008), with a strong focus on self-efficacy in chronic conditions (Lorig et al. 2003). Despite this, these domains are not routinely assessed in the current literature (O'Shea et al. 2016). The LIVELY PAI had a strong emphasis on promoting self-efficacy and incorporated a number of strategies to allow for assessment of receipt and enactment including the use of and training to use a pedometer, an activity diary, goal setting, provision of feedback to participants and problem solving to develop strategies to overcome barriers (Bellg et al. 2004). In the assessment of receipt, only three components were not fully received; the educational component (83.3% (5/6)), a recap on benefits of physical activity (33.3% (n=9/27)) and identifying strategies from the previous week that worked do more walking (76.6% (n=23/30)). There are currently no thresholds to determine how to define receipt treatment; in the LIVELY PAI a number of key strategies were included to enhance receipt and in our assessment nearly all of these were received. Future research should aim to develop a tool to assess and define the receipt of a PAI. In our assessment of enactment we attempted to address each item on the Borrelli (2011) checklist. The items to assess enactment in the Borrelli (2011) checklist were difficult to define in the context of the LIVELY PAI. It can be argued that the use of a pedometer satisfies the assessment of enactment as it allows for the assessment of a specific behavioural skill and motivational state (reaching step goals) in an appropriate setting (the participants own environment) (Bellg et al. 2004). This demonstrates the need for a more specific fidelity checklist for PAIs.

6.4.1 Limitations

Although executed systematically, this research is not without its limitations. Firstly the LIVELY PAI had already commenced prior to the development of the fidelity assessment

protocol. This limited our assessment of fidelity under some of the domains. For example the domain training of providers recommends that all providers are certified to deliver the intervention; this can be done through observing the provider delivering the intervention (either directly or with a video/audiotape) with a pilot patient and scoring them against pre-set criteria, providers must reach a minimum score before they are certified to deliver the intervention. Following certification between 20-50% of consultations should be reviewed and if the provider falls below a certain level of competency then additional training and feedback are required (Borrelli 2011). This certification was not done in the current study, planning for the assessment of fidelity prior to starting the intervention would ensure that such procedures are included. Previous authors have implemented these procedures, for example providers in a study conducted by Sears et al. 2013 had to reach 90% fidelity before they could implement the intervention and if they fell below 80% during the intervention they received additional training. Although the regular mentorship of providers in the LIVELY PAI, may have helped prevent any drift in skills. Future studies should include these strategies. Checklists to certify and monitor providers can be developed specific to the intervention or existing standardised checklists are available which can be used if applicable to the intervention for example the motivational interviewing skills code (Miller and Mont 2001) and the Behaviour Change Counselling Index (Lane et al. 2005).

The delay between commencing the intervention and the implementation of the fidelity assessment protocol also limited the number of audio recordings available for assessment. One third (n=75/221) of the consultations were conducted before the protocol for fidelity was implemented; the consultations that were recorded and used to assess fidelity were delivered in the latter part of the study. Assessing consultations that occurred earlier in the intervention would have allowed us to determine whether the providers were becoming more skilled in delivering the intervention over time or whether there was any drift in their skills and whether this had an impact on the participants receipt and enactment of treatment skills.

6.4.2 Lessons learned

The assessment of fidelity of the LIVELY PAI was novel and a number of key areas have been identified that should be addressed in a future study (Table 6.17). Some of the consultation recordings were lost due to recorder error, provider error and researcher

error; a future study should include processes that require the providers to check the recorder operating prior to the delivering the consultation, for example that it is charged and ready for use and all audio recordings should be sent to the research team within 24 hours of delivering the consultation. Additionally, using a yes/no tick box to assess delivery of the items did not reflect the quality of the delivery. A Likert scale rating the quality of the delivery could offer a stronger measure of how well the intervention was delivered per protocol. Borrelli (2011) considered this, but felt that the use of such a scale would introduce an element of subjectivity, making it difficult to suggest a valid conclusion. The use of two raters to assess delivery and clearly defining the criteria for each point on the scale would help eliminate any subjectivity. Previous authors have used a Likert scale to assess delivery; Bryant et al. (2014) assessed specific provider behaviours during their delivery and rated these on a 5 point like scale.

Assessing treatment fidelity is a time consuming and resource intense process. Once it was decided to use the Borrelli (2011) checklist as a framework for assessing fidelity, a considerable amount of time was spent planning the methods for the assessment of fidelity in the LIVELY PAI. Furthermore, time was spent reviewing the LIVELY PAI documents and mapping these to the specific consultations for the delivery, receipt and enactment checklists; these checklists were also assessed for practicality and acceptability before they were used in the rest of the study. Finally, conducting the assessment of fidelity required further time; the mean (SD) length of time for face to face consultations was 49.8(8.9) and 19.5 (2.8) minutes. In total 19 face to face audio recordings and 12 telephone audio recordings of consultations were assessed independently by two raters, and additionally paper based records for 5 consultations were reviewed (the recordings for these consultations were not obtained). This was a considerably time consuming process. The results were then synthesised and reported. Despite this lengthy and time consuming process, the assessment of fidelity was an invaluable process and future research should allocate appropriate time and funding to the assessment of fidelity.

Finally our fidelity assessment revealed that the components that were listed on the consultation schedule were delivered with higher fidelity than the BCSs; 96.7% (n=30/31) components on the consultation schedule compared to 70% (n=14/20) of BCTs were delivered with >80% fidelity. It is likely that the components on the consultation schedule were delivered with higher fidelity as the list of these was located at the beginning of each

consultation in the layout of the template so that providers could record their consultation notes. This structure also informed the layout and flow of the consulutation. The inclusion of the list of BCSs in the consultation schedule should be considered in a future trial to enhance the delivery of these.

6.5 Conclusion

Overall the fidelity of the LIVELY PAI was high. The assessment of fidelity is challenging with limited guidance on the specific procedures to use. This novel piece of research provides a working example using the Borrelli (2011) checklist for the assessment of fidelity. There were some limitations of our assessment of treatment fidelity and a number of key lessons have been learned regarding the process for assessing treatment fidelity.

Figures

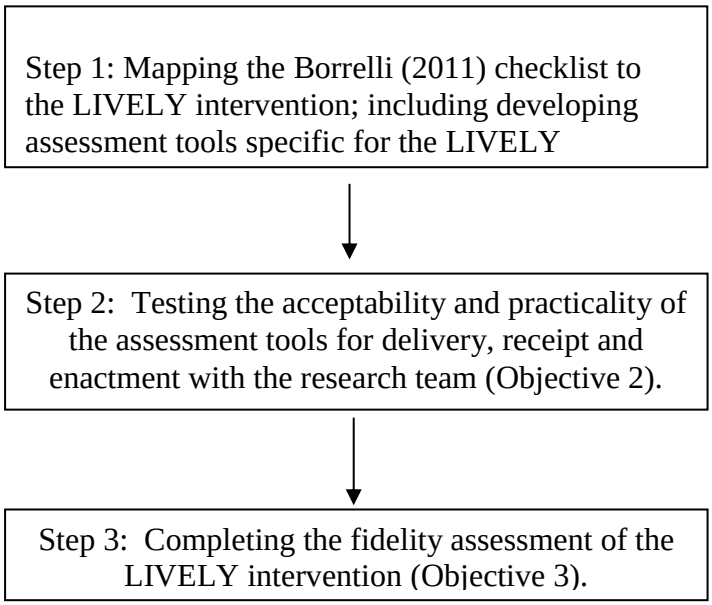

Figure 6-1 Flow diagram of methods for the assessment of treatment fidelity of the LIVELY intervention

Tables

Table 6-2 Proposed methods for mapping Borelli (2011) study design items to the LIVELY project

Borrelli (2011) checklist item	How this item is going to be achieved in the LIVELY project
1. Provider information about treatment dose in the intervention condition	
A. Length of contact (minutes)	Review of study documents*.
B. Number of contacts	Review of study documents.
C. Content of treatment	Review of study documents.
D. Duration of contact over time	Review of study documents.
2. Provide information about treatment dose in the comparison condition	
A. Length of contact (minutes)	Check of PR sites; self-reported.
B. Number of contacts	Check of PR sites; self-reported.
C. Content of treatment	Check of PR sites. self-reported.
D. Duration of contact over time	Check of PR sites. self-reported.
E. Method to ensure dose equivalent between conditions	Review of study protocol and self-reported check of PR sites.
F. Method to ensure dose is equivalent for participants within conditions	Review of study protocol and audit of PR sites.
3. Specification of provider credentials that are needed	
Exploration of study protocol.	
4. Theoretical model upon which the intervention is based is clearly articulated	
A. The active ingredient are specified and incorporated in the intervention	Review of study documents.
B. Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines	Review of team.
C. Plan to ensure that the measures reflect the hypothesise theoretical constructs/mechanisms of action	Review of study documents.
5. Potential confounders that limit the ability to make conclusions at the end of the trial are identified.	
Consensus among research team.	
6. Plan to address possible setbacks in implementation (i.e. back-up systems or providers)	
Review of study team and roles.	

* study documents refers to the full study protocol, the grant application, the PAI file and minutes of all study meetings

Table 6-3 Proposed methods for mapping Borrelli (2011) training of providers items to the LIVELY project

Borrelli (2011) checklist item	How this item is going to be achieved in the LIVELY project
1. Description of how providers will be trained (manual of training procedures)	Review of the training materials.
2. Standardisation of provider training (especially if multiple waves of training are needed for multiple groups of providers)	Review of the training materials.
3. Assessment of provider skill acquisition	Review of the training materials and of mentorship telephone calls.
4. Assessment and monitoring of provider skill maintenance over time	Review of the training materials and weekly mentorship telephone calls.
5. Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori	Review of study documents. *
6. At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g. ensure that providers find the intervention acceptable, credible and potentially efficacious)	Discussion among study team.
7. There is a training plan that takes into account trainees different education and experience and learning styles	Review training materials and a questionnaire to assess if the providers felt the training plan took into account their different education and learning styles was developed (Appendix 25, Evaluation of training of providers for the delivery of the LIVELY PAI-Provider feedback evaluation questionnaire,).

* study documents refers to the full study protocol, the grant application, the PAI and minutes of all study meetings

Table 6-4 Proposed methods for mapping Borrelli (2011) delivery of treatment items to the LIVELY project

Borrelli (2011) checklist item	How this item is going to be achieved in the LIVELY project
1.Method ensure that the content of the intervention is delivered as specified	Review of study documents*, assessment of audio recordings of consultations and provider notes with specifically developed checklists for LIVELY and mentorship programme.
2. Method to ensure the dose of the intervention is delivered as specified	Review of mentorship programme and provider notes.

3. Mechanism to assess if the provider actually adhere to the intervention plan	Plan for audio recording and provider notes with LIVELY specifically developed checklists for assessment of delivery created from review of study materials.
4. Assessment of nonspecific treatment affects	Discussion with research team.
5. Use of treatment manual	Review of study documents.
6.There is a plan for the assessment whether or not the active ingredient was delivered	Plan for audio recording and a LIVELY specific checklist for assessment of delivery created.
7.There is a plan for the assessment of whether or not the proscribed components were delivered (e.g. components that are unnecessary or unhelpful)	Discussion with research team.
8.There is a plan for how contamination between conditions will be prevented	Review of study documents.
9.There is a priori specification of treatment fidelity (e.g. providers adhere to >80% of components)	Discussion with research team.

* study documents refers to the full study protocol, the grant application and minutes of all study meetings

Table 6-5 Proposed methods for mapping Borrelli receipt (2011) of treatment items to the LIVELY project

Borrelli (2011) checklist item	How this item is going to be achieved in the LIVELY project
1. There is an assessment of the degree to which participants understand the intervention.	The study documents* were reviewed and a LIVELY specific checklist created.
2. There are specification strategies that will be used to improve participant comprehension of the intervention.	The study documents were reviewed and a LIVELY specific checklist created.
3. The participants' ability to perform the intervention skills will be assessed during the intervention process.	The study documents were reviewed and a LIVELY specific checklist created.
4.A strategy will be used to improve participants performance of intervention skills during the intervention period	The study documents were reviewed and a LIVELY specific checklist created.
5.multicultural factors are considered in the development and delivery of the intervention	The study protocol was reviewed.

* study documents refers to the full study protocol, the grant application, the PAI file and minutes of all study meetings

Table 6-6 Proposed methods for mapping Borrelli enactment (2011) of treatment items to the LIVELY project

Borrelli (2011) checklist item	How this item is going to be achieved in the LIVELY project
1. Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.	The study documents* were reviewed and a LIVELY specific checklist developed.
2. A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.	The study documents were reviewed and a LIVELY specific checklist developed.

* study documents refers to the full study protocol, the grant application, the PAI file and minutes of all study meetings

Table 6-7 Assessment of delivery, receipt and enactment, by provider and primary and secondary raters for each set of consultations

Provider	Provider 1	Provider 2	Provider 3
Participant	C224	C124	C113
Primary rater	OO'S	OO'S	OO'S
Secondary rater (s)	MA	SMcD: C1 and C2, BO'N: C3, C4, C7 and C8, JB: C6, C9, C10, C11 MA: C5 and C12)	MA

*C= Consultation

Table 6-8 Results of assessment of study design in LIVELY with the Borrelli 2011 checklist

Borrelli (2011) Item	Results of the LIVELY COPD project
1. Provider information about treatment dose in the intervention condition	
a. Length of contact (minutes)	PAI to be <1hour for face to face consultations, consultation 1 may last longer (1.5 hours) with telephone calls to be of shorter duration e.g. 10-20 minutes (Appendix 5, PAI file Sections 2, Consultation instructions page 4, on CD-ROM)
b. Number of contacts	12 (6 face to face and 6 telephone) (Appendix 5, PAI file, Section 2, LIVELY PAI principles and overview, page 1, on CD-ROM)
c. Content of treatment	The content of the treatment is detailed in the PAI file sections 1-7 (Appendix 5, PAI file, sections 1-7, on CD-ROM).

d. Duration of contact over time	Twelve weeks (Appendix 5, PAI file, Section 2, LIVELY PAI principles and overview, page 1, on CD-ROM)
2. Provide information about treatment dose in the comparison condition	
a. Length of contact (minutes)	Results of PR self-check (Appendix 33, Results of the pulmonary rehabilitation check of sites included in the LIVELY COPD project on CD-ROM).
b. Number of contacts	Results of PR self-check (Appendix 33, Results of the pulmonary rehabilitation check of sites included in the LIVELY COPD project on CD-ROM).
c. Content of treatment	Results of PR self-check (Appendix 33, Results of the pulmonary rehabilitation check of sites included in the LIVELY COPD project on CD-ROM).
d. Duration of contact over time	Results of PR self-check (Appendix 33, Results of the pulmonary rehabilitation check of sites included in the LIVELY COPD project on CD-ROM).
e. Method to ensure dose equivalent between conditions	Both groups received 12 contacts over the course of the PAI or PR. (LIVELY protocol: https://clinicaltrials.gov)
f. Method to ensure dose is equivalent for participants within conditions	PR site self-reported at start and middle of intervention that 12 contacts are still being provided to participants (Appendix 33, Results of the pulmonary rehabilitation check of sites included in the LIVELY COPD project on CD-ROM).
3. Specification of provider credentials that are needed	
This was restricted to personnel working in the Northern Irish Clinical Research Network (NICRN). Either respiratory nurses or physiotherapists with experience in PR were sought.	
4. Theoretical model upon which the intervention is based is clearly articulated	
a. The active ingredient are specified and incorporated in the intervention	The LIVELY PAI combined recommendations from the PA guidelines, influences from the stages of change and key behaviour change strategies were identified in advance which mapped to the theoretical model i.e. the COM-B model (Appendix 6, Amended list of BCS included in the LIVELY PAI) (BASES 2011, Marcus and Forsyth 2009, Michie et al. 2014).
b. Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying	An expert team designed the programme. There was consultation between physiotherapists, health psychologists, doctors and a patient was included on the steering group

theoretical model or clinical guidelines	
c. Plan to ensure that the measures reflect the hypothesise theoretical constructs/mechanisms of action	The outcome measures were chosen to actively assess the hypothesis and mechanisms of action (Appendix 2, LIVELY CRF, on CD-ROM).
5. Potential confounders that limit the ability to make conclusions at the end of the trial are identified.	
The LIVELY intervention was a feasibility study. Therefore the small sample size in addition to drop outs limited the ability to make conclusions about the effectiveness of the intervention.	
6. Plan to address possible setbacks in implementation (i.e. back-up systems or providers)	
Three providers were trained to deliver the intervention, to allow for cover for annual leave or unexpected absences. Providers were also supported by a mentor, site medical collaborator and research team to address any setbacks in implementation.	

Table 6-9 Results of assessment of training of providers in the LIVELY PAI with the Borrelli 2011 checklist

Borrelli (2011) Item	Results of the LIVELY COPD project
1. Description of how providers will be trained (manual of training procedures)	A plan for how the providers were to be trained was set out from the beginning (Appendix 5, PAI file, Section 9, Training, on CD ROM)
2. Standardisation of provider training (especially if multiple waves of training are needed for multiple groups of providers)	All providers were to attend the same training days delivered by the research team. Due to unforeseen circumstances one provider did not attend one of the sessions. However through the weekly mentorship programme it was thought that the impact of the missed training sessions could be minimised (Appendix 5, PAI file, Section 9, Training, on CD-ROM)
3. Assessment of provider skill acquisition	Provider skill acquisition was assessed through formative assessment and feedback during training by using mock case scenarios initially and then real study data (Appendix 5, PAI file, Section 9, Training, on CD-ROM).
4. Assessment and monitoring of provider skill	Assessment and monitoring of provider skill maintenance was carried out through regular training days throughout the study and the weekly

maintenance over time	mentoring phone calls Appendix 5, PAI file, Section 9, Training on CD-ROM).
5. Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori	Physiotherapists or respiratory nurse or working in the NICRN respiratory health network were sought. Characteristics to be avoided were not articulated (Appendix 35, Minutes of team meeting 12/12/12, on CD-ROM).
6. At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g. ensure that providers find the intervention acceptable, credible and potentially efficacious)	This was not applicable to our assessment as the research team was limited to those already working in the NICRN.
7. There is a training plan that takes into account trainees different education and experience and learning styles	The training planned to include theory, practical components, case scenarios, group work, and workshop style delivery to help support different training needs. There was also a mentorship plan in place; providers had weekly phone calls with an experienced colleague. A feedback evaluation questionnaire was completed by the providers at one time point to assess if they felt the training met these criteria.

Table 6-10 Results of assessment of delivery of treatment of the LIVELY PAI with the Borrelli 2011 checklist

Borrelli (2011) Item	Results of the LIVELY COPD project
1.Method ensure that the content of the intervention is delivered as specified	The mentorship programme helped to ensure that the content is delivered as specified. Pre consultation checklists and templates for documentation also helped to ensure that the content is delivered as specified.
2. Method to ensure the dose of the intervention is delivered as specified	Weekly contact with the mentor helped ensure that the dose of the intervention is delivered as specified. The provider notes were reviewed at the end of the intervention to assess the mean duration of the intervention and how many consultations did each participant receive.

3. Mechanism to assess if the provider actually adhere to the intervention plan	A sample of consultations were audio recording and with accompanying provider notes were assessed the delivery checklists. (Appendix 30, Amended delivery checklists, developed specifically for the assessment of fidelity of the LIVELY PAI)
4. Assessment of nonspecific treatment affects	Nonspecific treatment effects were not considered for the LIVELY intervention
5. Use of treatment manual	A treatment manual was specifically designed for and used in the LIVELY intervention (Appendix 5, LIVELY PAI file, on CD-ROM).
6.There is a plan for the assessment whether or not the active ingredient was delivered	A sample of consultations were assessed with the delivery checklists to see if these "active ingredients" were delivered (Appendix 30 Amended delivery checklists, developed specifically for the assessment of fidelity of the LIVELY PAI).
7.There is a plan for the assessment of whether or not the proscribed components were delivered (e.g. components that are unnecessary or unhelpful)	There was no plan for the assessment of proscribed components in the delivery; however during the assessment of audio recordings additional items that were not planned as part of the programme were noted, e.g. prescribing participants "rest days" from physical activity.
8.There is a plan for how contamination between conditions will be prevented	Participants did not meet each other during the intervention and each condition was delivered by separate providers.
9.There is a priori specification of treatment fidelity (e.g. providers adhere to >80% of components)	A set of key BCSs were identified for the LIVELY PAI, along with additional items on the consultation checklist. It was planned that providers would adhere to 80% of these components (Appendix 30 Amended delivery checklists, developed specifically for the assessment of fidelity of the LIVELY PAI).

Table 6-11 Results of the assessment of delivery of Behaviour Change Strategies by provider to a participant in the LIVELY PAI

LIVELY PAI BCS	Delivery by provider Mean			
Setting an overall walking (or functional) goal e.g. walking to sisters house or walking into town every day as a results of the increased step counts/physical activity **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
Provide information on the consequences of behaviour in general and for the individual and (pro/cons) of being more active (any risks of not being more active) **(Consultation 1,2,3,4,5,6,7,8,9,10,11,12)**	Provider 1 66.7% (8/12)	Provider 2 33.3% (4/12)	Provider 3 75% (9/12)	58.3%
Disease specific education. **(Consultation 1 and 5)**	Provider 1 100% (2/2)	Provider 2 50% (1/2)	Provider 3 100% (2/2)	83.3%
Discuss barriers to physical activity **(Consultation 2,3,4,5,6,7,8,9,10,11,12)**	Provider 1 72% (8/11)	Provider 2 90.9% (10/11)	Provider 3 100% (11/11)	63.9%
Training to use pedometer (including 20 step test) and completion of 7 day diary= skills/demonstration. **(Consultation 1)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
(a)Use pedometer steps in self-efficacy walk to set step goal **(Consultation 2,3,4,5,6,7,8,9,10,11)**	Provider 1 60% (6/10)	Provider 2 70% (7/10)	Provider 3 20% (2/10)	50%
(b) Use 7 day pedometer steps to set step goal **(Consultation 2,3,4,5,6,7,8,9,10,11)**	Provider 1 90% (9/10)	Provider 2 90% (9/10)	Provider 3 100% (10/10)	93.3%
Build self-efficacy focusing the patient's attention on where they have been able to do well and focus on achievements. **(Consultation 2,3,4,5,6,7,8,9,10,11,12)**	Provider 1 100% (10/10)	Provider 2 87.5% (7/8)	Provider 3 100% (10/10)	95.8%
Demonstrate appropriate walking pace during self-efficacy walk and Borg rating **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
Plan behaviour using action and coping plan**(Consultation 2,3,4,5,6,7,8,9,10,11)**	Provider 1 100% (10/10)	Provider 2 100% (10/10)	Provider 3 100% (10/10)	100%

Record daily steps with pedometer **(Consultation 2,3,4,5,6,7,8,9,10,11)**	Provider 1 100% (10/10)	Provider 2 100% (10/10)	Provider 3 100% (10/10)	100%
Review planned and actual walking behaviour each week with clinician by reviewing diary and pedometer daily step count and provide feedback **(Consultation 3,4,5,6,7,8,9,10,11,12)**	Provider 1 100% (10/10)	Provider 2 100% (10/10)	Provider 3 100% (9/9)	100%
Review if goal met, not met or partially met **(Consultation 3,4,5,6,7,8,9,10,11,12)**	Provider 1 100% (10/10)	Provider 2 100% (10/10)	Provider 3 100% (10/10)	100%
Reward success/effort **(Consultation 3,4,5,6,7,8,9,10,11,12)**	Provider 1 100% (9/9)	Provider 2 57.1% (4/7)	Provider 3 100% (9/9)	85.7%
Certificate of achievement **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 0% (0/1)	Provider 3 0% (0/1)	33.3%
Clinician encourages social support, walking with friends/family or walking to meet somebody etc. **(Consultation 2,3,4,5,6,7,8,9,10,11,12)**	Provider 1 54.5% (6/11)	Provider 2 27.3% (3/11)	Provider 3 63.6% (7/11)	48.5%
Week 12 refer back, also review past success and also in terms of successful strategies. **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
Plan for relapse prevention **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
Materials manual i.e. LIVELY patient manual (includes diary) and LWWCOPD for PR (Consultation 1,2,3,4,5,6,7,8,9,10,11,12)	Provider 1 83.3% (10/12)	Provider 2 41.6% (5/12)	Provider 3 100% (12/12)	74.9%
Review SMART goal **(Consultation 6,12)**	Provider 1 100% (2/2)	Provider 2 50% (1/2)	Provider 3 100% (2/2)	83.3%

Table 6-12 Results of the assessment of delivery of the components on the consultation schedule by provider to a participant in the LIVELY PAI

LIVELY PAI Consultation Plan	Delivery by provider			Mean
1.Report on patients health status and record any adverse events **(Consultation 1,2,3)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
2.Explain the goal of the programme **(Consultation 1)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%

3.Mention general benefits of physical activity **(Consultation 1)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
4.Familiarise patient with pedometer**(Consultation 1)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
5.Do 20 step test **(Consultation 1)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
6.Explain step diary **(Consultation 1)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
7.Educational component **(Consultation 1 and 5)**	Provider 1 100% (1/1)	Provider 2 50% (1/2)	Provider 3 100% (1/1)	83.3%
8.Remind patient of goal of the programme **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 0% (0/1)	Provider 3 100% (1/1)	66.6%
9.Discuss benefits of PA **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
10.Set SMART goal **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
11.Note any problems with pedometer **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
12.Record steps for the familiarisation week **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
13.Do self-efficacy walk **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
14.Set step goal for the week **(Consultation 2)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
15.Complete action and coping plan **(Consultation 2,3,4,5,6,7,8,9,10,11)**	Provider 1 100% (11/11)	Provider 2 100% (11/11)	Provider 3 100% (11/11)	100%
16.Any barriers discussed **(Consultation 2,3,4,5,6,7,8,9,10,11)**	Provider 1 80% (8/10)	Provider 2 90% (9/10)	Provider 3 100% (10/10)	90%
17.Assess patient confidence level **(Consultation 2,3,4,5,6,7,8,9,10,11)**	Provider 1 100% (10/10)	Provider 2 100% (10/10)	Provider 3 90% (9/10)	96.6%
18.Patient progress reviewed **(Consultation 3,4,5,6,7,8,9,10,11)**	Provider 1 100% (9/9)	Provider 2 100% (9/9)	Provider 3 100% (9/9)	100%
19.New goal set and inserted in diary **(Consultation 3,4,5,6,7,8,9,10,11)**	Provider 1 100% (9/9)	Provider 2 100% (9/9)	Provider 3 100% (9/9)	100%
20.Review SMART goal **(Consultation 6,12)**	Provider 1 100%	Provider 2 50%	Provider 3 100%	83.3%

	(2/2)	(1/12)	(2/2)	
21.Step count inserted in chart **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
22.Summary of 12 week steps inserted **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
23.Review progress from week 1 **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
24.Benefits of walking re-enforced **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
25.Discuss maintenance strategies **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
26Summary of barriers and successful strategies inserted **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
27.Other relapse prevention inserted **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
28.Relapse prevention due to COPD exacerbation advice given **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 0% (0/1)	Provider 3 100% (1/1)	83.3%
28.Plan for continuing maintenance discussed **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
29.Resources for additional walking given **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%
30.Complete physical activity intervention patient progress summary **(Consultation 12)**	Provider 1 100% (1/1)	Provider 2 100% (1/1)	Provider 3 100% (1/1)	100%

Table 6-13 Results of assessment of treatment receipt of the LIVELY PAI with Borrelli 2011 checklist

Borrelli (2011) Item	Results of the LIVELY COPD project
1. There is an assessment of the degree to which participants understand the intervention.	The LIVELY PAI file was explored to determine how this was being met, checklists were developed and the audio recordings and provider notes reviewed to assess receipt (Appendix 5 LIVELY PAI file, on CD-ROM)
2. There are specification strategies that will be used to improve participant comprehension of the intervention.	The LIVELY PAI file was explored to determine how this was being met, checklists were developed and the audio recordings and provider notes reviewed to

	assess receipt (Appendix 5 LIVELY PAI file, on CD-ROM)
3. The participants' ability to perform the intervention skills will be assessed during the intervention process.	The LIVELY PAI file was explored to determine how this was being met, checklists were developed and the audio recordings and provider notes reviewed to assess receipt (Appendix 5, LIVELY PAI file, on CD-ROM)
4.A strategy will be used to improve subject performance of intervention skills during the intervention period	The LIVELY PAI file was explored to determine how this was being met, checklists were developed and the audio recordings and provider notes reviewed to assess receipt (Appendix 5 LIVELY PAI file, on CD-ROM)
5.multicultural factors considered in the development and delivery of the intervention	The study excluded anybody who could not read or speak English. The programme was individualised so as factors outside of this could be incorporated (LIVELY protocol https://clinicaltrials.gov/).

Table 6-14 Results of the assessment of receipt of the LIVELY PAI by three participants

Item 1: An assessment of the degree to which the participant understands the intervention					
(i)	Familiarisation week; Demonstration of patient using pedometer and the 7 day recall **(Week1)**	P*1 100% (1/1)	P2 100% (1/1)	P3 100% (1/1)	100%
Item 2:There is a specification of the strategies that will be used to improve participant comprehension of the intervention					
(i)	General benefits of exercise discussed **(consultation 1)**	P 1 100% (1/1)	P2 100% (1/1)	P3 100% (1/1)	100%
(ii)	Educational components **(consultation 1 and 5)**	P 1 100% (1/1)	P2 50% (1/2)	P3 100% (1/1)	83.3%
(iii)	Reaffirm physical activity levels and benefits **(consultation 2)**	P 1 100% (1/1)	P2 100% (1/1)	P3 100% (1/1)	100%
(iv)	Recap on benefits of physical activity **(consultation 3,4,5,6,7,8,9,10,11)**	P 1 22.2% (2/9)	P2 22.2% (2/9)	P3 55.5% (5/9)	33.3%
(v)	Familiarisation week **(week 1)**	P 1 100% (1/1)	P2 100% (1/1)	P3 100% (1/1)	100%

(vi)	Self-efficacy walk **(consultation 2)**	P 1 100% (1/1)	P2 100% (1/1)	P3 100% (1/1)	100%
(vii)	Weekly contact***(consultation 1,2,3,4,5,6,7,8,9,10, 11,12)**	P 1 100% (12/12)	P2 100% (12/12)	P3 100% (12/12)	100%
(viii)	Action coping plan **(consultation 2,3,4,5,6,7,8,9,10,1 1)**	P 1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%
(ix)	Goal setting for step count with the pedometer **(consultation 2,3,4,5,6,7,8,9,10,1 1,12)**	P 1 100% (11/11)	P2 100% (11/11)	P3 100% (11/11)	100%
Item 3:The participants' ability to perform the intervention skills will be assessed during the intervention process					
(i)	Review progress assessing whether the step targets were met **(consultation 3,4,5,6,7,8,9,10,11, 12)**	P 1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%
(ii)	Use of tools: pedometer and step diary **(consultation 3,4,5,6,7,8,9,10,11, 12)**	P 1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%
Item 4:A strategy will be used to improve participant performance of the intervention skills during the intervention					
(i)	Set a step goal **(consultation 2)**	P 1 100% (1/1)	P2 100% (1/1)	P3 100% (1/1)	100%
(ii)	Complete action and coping plan **(consultation 2,3,4,5,6,7,8,9,10,1 1)**	P 1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%
(iii)	Assess level of confidence **(consultation 2,3,4,5,6,7,8,9,10,1 1)**	P 1 100% (9/9)	P2 100% (9/9)	P3 100% (9/9)	100%
(iv)	Reset walking goal **(consultation 3,4,5,6,7,8,9,10,11)**	P 1 100% (9/9)	P2 100% (9/9)	P3 100% (9/9)	100%

(v)	Revisit step target as per previous week **(consultation 3,4,5,6,7,8,9,10,11, 12)**	P 1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%
(vi)	Identify strategies from the previous week that worked do more walking **(consultation 3,4,5,6,7,8,9,10,11, 12)**	P 1 90% (9/10)	P2 40% (4/10)	P3 100% (10/10)	76.6%
Item 5:Multicultural factors considered in the development of the delivery **(Throughout the intervention)**					
No; but the intervention was very much individualised and could be easily tailored to incorporate any of these factors. For example C124 was involved in marching and this was incorporated in the programme.					

*P=participant

Table 6-15 Assessment of treatment enactment of the LIVELY project with the Borrelli (2011) checklist

Borrelli (2011) Item	Results of the LIVELY COPD project
1. Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.	The LIVELY PAI file was examined to explore how this was being met, checklists were made and the audio recordings and providers notes examined to assess enactment (Appendix 5, LIVELY PAI file, Sections 1-7, on CD-ROM)
2. A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.	The LIVELY PAI file was examined to explore how this was being met, checklists were made and the audio recordings and providers notes examined to assess enactment (Appendix 5, LIVELY PAI file, Sections 1-7, on CD-ROM)

Table 6-16 Results of the assessment of enactment of treatment skills of the LIVELY PAI by participants

Item 1: Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied				
(i)	Does the step diary match the 7 day recall **(consultation 2)**	P*1 100% (1/1)	P2 0% (0/1)	P3 N/A	50%
(iia) A review and report of the participants step count is completed **(consultation 3,4,5,6,7,8,9,10,11,12)**		P1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%
(iib) A review and report of whether the participant met their step goal is completed **(consultation 3,4,5,6,7,8,9,10,11,12)**		P1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%
(iic) A review of the extent to which the participant followed their action plan is completed **(consultation 3,4,5,6,7,8,9,10,11,12)**		P1 90% (9/10)	P2 60% (6/10)	P3 60% (6/10)	70%
Item 2: A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied				
(i)A step diary and pedometer are provided for one week to allow the participant to familiarise themselves with these tools **(consultation 2)**		P1 100% (1/1)	P2 100% (1/1)	P3 100% (1/1)	100%
(ii)A step count is recorded and reported **(consultation 3,4,5,6,7,8,9,10,11,12)**		P1 100% (10/10)	P2 100% (10/10)	P3 100% (10/10)	100%

P*=participant

Table 6-17 Summary of key lessons learned that should be considered in future research for the assessment of treatment fidelity of an intervention

(i)	allocate adequate funds for the assessment of fidelity within proposals;
(ii)	include a detailed fidelity protocol within the trial protocol;
(iii)	train providers on the purpose of and the importance of assessing treatment fidelity;
(iv)	test any checklists developed specific to the intervention for practicality and acceptability;
(v)	adapt the Borrelli checklist to suit their type of intervention,

Chapter 7 - Discussion

7.1 Introduction

The focus of this PhD was on PA in people with COPD. Higher levels of PA are associated with improved health outcomes in this population (Garcia-Ayermich et al. 2009). There is strong evidence to demonstrate that people with COPD engage in lower levels of COPD compared to their healthy counterparts (Park et al. 2013, Troosters et al. 2010a, Hernandes et al. 2009, Pitta et al. 2005). PR, the mainstay treatment for PA in people with COPD, does not always result in increased levels of PA (Troosters et al. 2010b, Bolton et al. 2013, Spruit et al. 2013). In more recent years there has been an increased focus in exploring interventions to enhance PA in people with COPD (Wilson et al. 2014). Therefore the LIVELY COPD project aimed to investigate the feasibility of conducting a clinician facilitated pedometer driven walking intervention versus PR (usual care) in improving PA in people with COPD. This PhD was fully embedded within this project. There were two key aims in this PhD (1) to assess the feasibility of conducting a trial to explore the effectiveness of a pedometer driven clinician facilitated PAI versus PR in improving PA in COPD patients referred to PR (the LIVELY COPD project); and (2) to assess the treatment fidelity of the LIVELY PAI.

There were three key findings of this research. Firstly, conducting a mixed methods feasibility trial was a valuable process. A number of important lessons were learned from conducting this feasibility study that need to be considered before progressing to a future large scale trial. For example in the LIVELY COPD project, we experienced a high rate of drop outs; although there were less dropouts in the PAI group compared to the PR group, we need to consider the reasons for this to help reduce dropouts in both groups in future. The primary outcome measure in the LIVELY COPD project was step count from the ActiGraph, which presented challenges in terms of the resource intense analysis and some data loss and we would therefore need to explore the best method for the assessment of PA. Secondly the LIVELY PAI was feasible and may provide a viable option for COPD patients in the NHS in addition to PR. The third key finding of this PhD was that the assessment of fidelity was beneficial. The assessment of treatment fidelity of the LIVELY COPD project was a challenging and resource intensive, yet important, process; assessing and monitoring treatment fidelity should be considered central to all future

studies assessing a complex intervention. There were other findings that were also important for clinical practice and which should be taken into account when planning a future trial for PA in COPD.

This chapter will discuss these findings and outline the implications for future research. It will also discuss the implications for clinical practice.

7.2.1 Main finding 1 and implications for future research

The use of a mixed methods feasibility design was a valuable process: A mixed methods feasibility study design was chosen for the LIVELY COPD project as recommended by the MRC, the NIHR and other key publications (Craig et al. 2006, Thabane et al. 2010, Lancaster 2015, NIHR 2012). The NIHR criteria were utilised to report the success of this study; the results of the LIVELY COPD project indicated it was feasible to move forward to a full RCT. However important lessons need to be taken into consideration.

Firstly, recruitment and randomisation were deemed to feasible in the current trial; we planned to recruit over a period of 14 months and achieved target at 16 months. In the LIVELY COPD project, 651 patients were screened, and 50 of these consented and were randomised. Other trials reporting on PAIs in COPD have reported more variable recruitment rates, for example Berry et al. 2003 screened 775 patients for eligibility and recruited 140 of these and elsewhere Varga et al. 2007 reported screening 79 patients for eligibility and recruited 71 of these patients. The numbers patients who were screened was carefully documented and reported in the LIVELY COPD project as part of the feasibility criteria (NIHR 2012). The reporting of screening is not part of the CONSORT checklist (2010) (Schulz et al. 2010) for reporting RCTs, however information on this has been proposed as an extension of the CONSORT checklist for a reporting of feasibility and pilot studies (Thabane et al. 2016). More recently Chaplin et al. 2017 reported screening 2646 for eligibility and 103 of these were recruited to a randomised controlled feasibility trial for an interactive web based PR programme versus conventional PR for people with COPD. Screening and recruitment rates should be more transparently reported not only in feasibility studies but also in RCTs to allow for better comparison between different recruitment procedures and populations. In terms of randomisation, the qualitative analysis revealed that almost all patients were happy with their allocation and enjoyed their respective programme (Chapter 4). The qualitative component of this mixed

methods trial was therefore important in determining the feasibility of the LIVELY COPD project.

Secondly, there were high levels of dropouts in the LIVELY COPD project. There were fewer dropouts in the PAI group compared to the PR group. Dropouts from the PR group (52%) were a lot higher than those reported in a recent audit from England and Wales (29%) (Steiner et al 2016). The reasons for this are unclear, and as stated in Chapter 3, this study was not developed to specifically explore the reasons for dropouts. The $FEV\%_1$ predicted of the PR group in the LIVELY COPD project is similar to that reported in the audit (53% versus 54%) (Steiner et al. 2016) and it is possible that the patients in the current study had a higher rate of comorbidities; there were no patients in the current study without comorbidities compared with 14% of patients in the audit conducted by Steiner et al. (2016). Differences such as the presence of comorbidities might go some way to explaining the difference in these dropout rates. In addition to this, the NI COPD population has the lowest levels of PA among various other COPD populations, including the Republic of Ireland, Belgium and the United States (O'Shea et al. 2015). There is no published data of the PA levels in people with COPD for the rest of the UK. These high rates of dropouts from PR coupled with the low PA levels indicate that the COPD population of NI in this study may have had some different characteristics to other populations. For example NI is recognised as an area of low socieconomic status (EU Inequality Briefing 43, 2014), and lower socieoconomic status is associated with higher rates of drop out from PR (Steiner et al. 2017). However further research is warranted to investigate this. Finally the qualitative analysis provided some insight into the reasons for dropout for example some patients did not like the group setting (Chapter 4). The qualitative analysis did not capture the views of all those who dropped out and was limited only to those who were willing to return for outcome measure assessment. Future research should focus on developing strategies to optimise retention and reduce dropouts.

Thirdly, important information on the outcome measures was obtained. PA was measured objectively using two different devices: a sealed pedometer and the ActiGraph worn on a belt around the waist. As discussed in Chapter 3, the ActiGraph is a more precise measure of PA (O'Neill et al. 2017a). The available data from the ActiGraph was reduced due to participants not meeting the wear time criteria. There are some aspects of objective PA measurement that could be explored to maximise this data. The wear time rules used for

the COPD population could be less stringent. In the LIVELY COPD project, we followed the rules for wear time from Byron and Rowe (2016), who recommend using five days of ten hours wear time for PA data in COPD. This review also found that wear time criteria is not routinely reported in the literature and there are also other reports and guidelines advising that less days and hours are acceptable to measure free living PA; as little as eight hours over 4 days has been recommended in both healthy people (Hagstromer and Sjostrom 2010) and the COPD population (Demeyer et al. 2014). Demeyer et al. 2014 have also suggested that daylight hours should be considered as a covariate in the analysis. There is a need for greater consistency in the reporting of wear time and the publication of guidelines for wear time criteria for activity monitors in people with COPD, as their daily habits may differ from healthy individuals. The wear time algorithm in ActiLife (Choi et al. 2011) was developed for the healthy adult population; it is possible periods of prolonged sedentary behaviour may be classified as non-wear time in people with COPD. Finally, the use of a monitor worn on a different part of the body, such as the wrist, could increase wear time in the COPD population. The qualitative data in the current study revealed that a small number of participants did not enjoy wearing the device around their waist. There are a range of validated monitors available for assessing PA in people with COPD that could be considered in a future study, for example the ActiGraph can be worn on the waist, the DynapPort worn on the lower back, the SenseWear worn on the upper arm and the Fitbit worn on the wrist (Voojis et al. 2014). Future research should consider exploring where people with COPD find it most acceptable to wear an activity monitor.

Furthermore objective PA data was reduced as some participants were unwilling to travel for re assessment and only completed the paper based outcome measures. There was therefore more available data for IPAQ compared to the ActigGraph. The IPAQ is a paper based outcome measure and participants who did not wish to return could complete this outcome measure by post. The IPAQ is a valid and reliable method of assessing PA (Craig et al. 2003), and had previously been used in people with COPD (Parada et al 2011, Ianal-Ince et al. 2014). However, the results of the LIVELY COPD project indicate that the IPAQ may not produce results comparable to that of the objective measurement; 18% (n=9/50) of participants were classified as highly active by the IPAQ at baseline, n=3/41 (7%) of participants were classified as somewhat active by the ActiGraph step count at baseline. Additionally, recent evidence in patients with bronchiectasis has indicated that

the IPAQ is not an accurate method of assessing PA in people with bronchiectasis (O'Neill et al. 2017a). Furthermore a recent report has found that self-reported PA is not reliable for measuring time spent in moderate PA in people with COPD (Sievi et al. 2017). There is therefore considerable evidence that PA in people with COPD should not be assessed by self-report questionnaires in a research setting. When exploring patients views on the outcome measures in the LIVELY COPD project some patients felt the questionnaires were complicated. Future research assessing PA in COPD patients should only consider objective measurements of PA.

7.2.2 Main Finding 2 and implications for future research

The PAI appeared to be feasible in terms of the ability to train clinicians to deliver the intervention (providers), the successful delivery of the intervention (i.e. participants could achieved their weekly step goals) and acceptability of the intervention.

Three providers were trained to deliver the intervention and this was feasible. Training was conducted before the intervention commenced and throughout the intervention as planned. The providers were also mentored in delivery of the intervention throughout. The training of providers was explored in further detail in Chapter 6.

In Chapter 3, we explored the feasibility of the intervention in terms of whether participants could achieve their weekly step goals and the overall improvement. The mean change in step count is in line with the MCID for this population; however given the feasibility nature of this trial we cannot draw any conclusions regarding the effectiveness of the LIVELY PAI. This adds to the current research that PAIs can increase PA in people with COPD (Wilson et al. 2014). However as these PAIs have not been translated into clinical practice, PR remains the only form of exercise treatment for people with COPD in the NHS. Recently, Mantaoni et al. (2016) identified the components of a PAI that are effective in increasing PA levels in people with COPD, including BCS and a self-monitoring device such as a pedometer; these were included in the LIVELY PAI. The research challenge now is developing a PAI with the successful components that can be easily translated into clinical practice in a cost effective manner. The LIVELY PAI is estimated to take approximately double the length of time to deliver as the PR, which would place considerable strain on the NHS resources. The LIVELY PAI has already been adapted for people with bronchiectasis and delivered in the health service as a six

week intervention, with encouraging results, with both the HCPs and patients providing positive feedback (O'Neill et al. 2017b). The implementation of the LIVELY COPD PAI in clinical practice is therefore possible. Cost reducing modifications to the intervention, for example increased telephone contact, and would require assessment in a research setting prior to implementation in routine clinical practice. Further methods that could reduce the time of delivering the PAI have been discussed in Chapter 3.

The results of the qualitative exploration of the participants' views of the PAI provide further confirmation of the feasibility of the PAI in terms of the acceptability (Chapter 4). These results revealed that nearly all participants enjoyed the intervention, which is an important measure of acceptability. In addition to this we explored participants' views and satisfaction of the content and delivery of the programme; the combination of phone and telephone contact was well received with some participants expressing a preference for one mode over the other or felt they could have transitioned to the telephone contact earlier. The participant materials for the PAI were viewed positively; participants found the pedometer motivational and the LIVELY patient manual useful. COPD patients' views of a PAI have not yet been explored; in the LIVELY COPD project this qualitative data was important in making pragmatic decisions regarding the feasibility of the intervention.

7.2.3 Main finding 3 and implications for future research

The assessment and monitoring of treatment fidelity is an essential component when developing and implementing an intervention. This should be included in both a feasibility study and a full RCT. The review conducted within this PhD concluded that treatment fidelity is inconsistently defined and reported in the literature and recommended that a checklist, for example like that published by Borrelli 2011, could be used in future research to allow for the complete consideration of treatment fidelity. The Borrelli (2011) checklist was therefore used to develop a framework to assess the treatment fidelity of the LIVELY PAI. Treatment fidelity had not previously been assessed in a PAI for patients with COPD.

The Borrelli (2011) checklist provides a useful and practical framework for assessing fidelity. However this requires increased resources for assessing and monitoring treatment fidelity (Bellg et al. 2004). This increased requirement on time, equipment and

personnel has been proposed as a possible explanation for the paucity of the assessment of treatment fidelity in the literature (Bellg et al. 2004). As outlined in Chapter 6, a considerable amount of time was spent planning for and conducting the assessment of fidelity of the LIVELY PAI. However important lessons were learned regarding the methods for assessing fidelity of an intervention and regarding the content and delivery of the LIVELY PAI (Chapter 6). Therefore the assessment of fidelity of the LIVELY PAI may not only inform a future trial, but the dissemination of the methods used and lessons learned by the study team may help promote learning in the wider research community regarding the assessment and reporting of treatment fidelity, ultimately enhancing the quality of research and the translation of research into clinical practice.

7.2.4 Other key findings

(i) Not all participants who adhere to PR achieve clinical benefit (Garrod et al. 2006). In the LIVELY COPD project the number of participants in the PR group achieving the MCID for the ISWT and CAT was below that observed in a recent audit of PR in England and Wales (Steiner et al. 2015) (Chapter 3). Although this was a feasibility study and the numbers who adhered to PR were low, this coupled with the high rate of dropout, should be considered when planning future research. Future research may need to consider quality assurance measures to optimise PR programmes and a process to monitor the fidelity of PR delivered within a trial to ensure that true comparisons can be made. Additionally the identification of phenotypes for patients at increased risk of dropout for example those from a lower socioeconomic status (Steiner et al. 2017) would allow for targeted strategies aimed at increased adherence in these at risk patients. Such strategies could include arranging transport for PR and reminder weekly phone calls about PR.

(ii) A key finding of the qualitative component of the LIVELY COPD project was that patients had clear preferences for different aspects of the PAI and of PR, for example some participants enjoyed the group aspect of PR where as others did not. Most of the participants in the PAI found the pedometer motivating but a small number did not enjoy wearing it and found it to be too much pressure. There is therefore a need to explore what forms of PA people with COPD want to engage in or their preferred platform of delivery. Research in healthy individuals has demonstrated that even healthy individuals have a preference for what type of PA they wish to engage in, Booth et al. 1997 surveyed healthy adults in Australia to explore their preferred type of PA and support, for example whether

they would like to exercise in a group. The results of this study demonstrated that walking was the preferred type of activity and the type of support depended on age, with the younger groups expressing a desire to exercise as part of a group and older adults preferring to receive advice. There is a need for a similar type of research to be conducted in people with COPD as the single approach i.e. traditional PR is not meeting the needs of all patients with COPD, evidenced through the poor uptake and dropouts (Steiner et al. 2015). Aside from patient preferences there are problems with accessibility with a PR programmes are not available to a large number of patients with COPD (Steiner et al. 2016, Rochester et al. 2015) and some PR programmes do not accept patients until they are at a more severe stage of the disease (Steiner et al. 2015). Clarenbach et al. 2017 have demonstrated the need for early PA intervention for people with COPD, as every year PA decreases by approximately 500 steps. Alternative platforms for delivering PR have been explored; Chaplin et al. (2017) have explored a web based platform for delivering PR to people with COPD. The feasibility of delivering a web based PR programme in comparison to conventional PR was assessed. No statistical difference in the outcome between the two groups was found and it was recommended that future research investigate choice for people with COPD and allow for better stratification of patient care. Furthermore Demeyer et al. 2017, investigated the effectiveness of a 12 week semi-automated telecoaching intervention compared with usual care (the usual care group received a standard leaflet explaining the importance of PA in COPD as well as information about PA recommendations). The intervention group received one face to face PA counseling consultation and step counter. All step counts were uploaded remotely and step goals updated remotely. The investigators only made telephone contact with participants in cases of noncompliance or failure to progress. This telecoaching intervention was found to be effective in improving PA in people with COPD. Those with less symptoms and higher exercise capacity at baseline had a more favourable response; this reinforces the need for stratification of patient care. Providing patients with increased choices for exercise/PA training, at an earlier stage in their disease trajectory is paramount to help COPD patients maintain optimum levels of PA and reduce the frequency of exacerbations, comorbidities, hospitalisations and mortality. The provision of choice and different platforms for delivering and modes of PA also fits in with the NHS strategy for personalised medicine (NHS England 2016).

7.3 Implications for clinical practice

The implementation of interventions that have been proven to be effective in research into clinical practice on a trial basis would help enhance choice for patients with COPD as well as potentially facilitating earlier intervention. Examples such as the LIVELY PAI (Chapter 3), web based PR and telecoaching (Chaplin et al. 2017, Demeyer et al. 2017); provide potentially feasible platforms for delivery in the clinical setting. Interventions that are delivered remotely do not require as much resources as traditional PR in terms of personnel and could also be potentially more cost effective. Furthermore these types of interventions may be more feasible to personalise or may be more practical for patients who have transport difficulties or are still in employment and unable to attend class at specific times. Increasing choice and adding new models of PA/exercise training would require increased resources such as training clinicians to implement in clinical practice.

There are at present no guidelines for the components of or how to deliver a PAI to people with COPD. The components of PAIs in the current literature are variable (Wilson et al. 2014) and may not be easily implemented in clinical practice. We plan to disseminate the materials for the LIVELY PAI, for COPD including the patient manual, chart and provider PAI file with instructions on how to deliver the intervention. Training will be made available to those who request it. This will provide clinicians with the opportunity to deliver a PAI to patients who PR may not be suitable for, they would also have the choice of attending the group based education.

PR programmes in NI, may need to consider implementing quality assurance procedures to reduce drop outs and optimise patient outcome. Implementing procedures such as phoning patients to remind them about the class or phoning patients when they have missed a class may help reduce these dropouts. Furthermore, exploring reasons for dropout with patients may help PR programmes implement changes that would reduce dropouts, for example in the LIVELY COPD project one of the reasons that contributed to a patient dropping out from PR was that they did not like the music in the class. Allowing patients to have some input into the music, is a simple modification that may help reduce drop outs in the future. Some patients dropped out from PR in the LIVELY COPD project due to poor health, following these patients up and restarting them in PR when they are well may also help reduce drop outs rates.

The current BTS and American Thoracic Society/ European Respiratory Society (ATS/ERS) guidelines for PR recognise that PR does not always results in increased levels of PA (Bolton et al. 2013, Spruit et al. 2013). The BTS guidelines therefore advise encouraging regular PA, five times a week for 30 min each time (Bolton et al. 2013, Spruit et al. 2013). However the assessment of PA as an outcome measure of PR is not included in the BTS guidelines for PR (Bolton et al. 2013) and the ATS/ERS guidelines do include information on assessing PA (Spruit et al. 2013). A recent audit of the PR services in England and Wales found 11% of programmes assess PA with an activity monitor. Step count is a simple metric of PA that is easily understood, and pedometers offer a cost effective method of assessing PA. Participants in the PR group were interested in their step count and seeing the change/improvement in step count from baseline to post intervention (Chapter 4). Clinicians should consider using step count from a pedometer as an outcome measure for PR.

7.4 Conclusion

This programme of research explored the feasibility of conducting a trial to explore the effectiveness of a pedometer driven clinician facilitated PAI versus PR in improving PA in COPD patients referred to PR (the LIVELY COPD project). A mixed methods randomised controlled design was chosen and the fidelity of delivering this intervention was also assessed. The results of this research indicate that the LIVELY COPD project was feasible to progress towards an RTC and the intervention was delivered with good fidelity. The inclusion of the qualitative component provided added learning regarding the feasibility of the LIVELY COPD project and enriched the results. There are a number of important considerations for future research, both for the LIVELY COPD project and for future research to enhance PA in the COPD population and for clinical practice.

A future RCT will require strategies to increase recruitment. Strategies will also be required to reduce dropouts from both the PAI group and from PR. Treatment fidelity will need to be considered in the design phase of the trial using the Borrelli (2011) checklist, allowing for the allocation of adequate resources. Additionally future research will need to consider quality assurance and fidelity measures for PR to ensure it is being delivered as intended. Finally the research team will need to consider what is the optimal method for assessing PA, taking factors such as the positioning of the monitor and wear time rules into consideration.

Future research to promote PA in patients with COPD should focus on identifying phenotypes of patients to allow for stratification of patient care. Current research has identified some phenotypes that may result in better adherence to an intervention, for example Demeyer et al. 2017 reported that patients with a better exercise capacity and less symptoms were more responsive to a telecoaching intervention and Steiner et al. 2017 reported that patients with a lower socioeconomic status are more likely dropout of PR. Furthermore the results of the LIVELY COPD project indicated that some patients had clear preferences for exercise for example the group setting was a reason dropping out of PR for some patients. In addition to this current research recommended that future research should investigate COPD patients' preferences (Chaplin et al. 2017). The identification of phenotypes as well what preferences patients with COPD have for PA/exercise will help the better stratification of patients, provision of care and optimise outcomes.

PR is currently the only method of PA/exercise training offered to people with COPD in the current health care structure. Future research should focus on the role of personalised exercise/PA interventions for COPD, how best to stratify patients and the translation of effective interventions into clinical practice.

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APPENDIX 3

ACTIVITY MONITOR PARTICIPANT INSTRUCTION MANUAL

Activity Monitor Participant Instruction Manual

General Instructions

1) All of the activity monitors should be worn for seven full days in a row during waking hours
2) **Please take off the activity monitors during night-time sleeping** and put them on again each morning after you wake up. You need to make sure each device is placed in the same position every time it is taken off **(it may be useful to set the activity monitors beside your keys / wallet / phone so that you remember to attach them the next day).**
3) If you usually take a nap during the day, please keep the activity monitors on during this time.

Please remove the activity monitors when you have a shower/bath because they are not waterproof. Put them on again straight away after your shower/bath.

Using the ActiGraph

Picture 1

1) You should wear the ActiGraph (Picture 1) which is attached to the ActiGraph belt on the hip area of the waist on your dominant side (i.e. _____ side) (Picture 2).

2) The device must fit snugly against your body to prevent errors when recording data **(Please note the device can be worn above or beneath clothing so does not have to be worn against the skin).**

Please make sure the monitor sits level on your waist as in Picture 2 and is not tilting forwards or to the side.

Picture 2

3) The green light flashing on the ActiGraph is normal, and indicates that everything is working properly and that it is on standby. **Note – do not worry if there is NO light flashing as this means the monitor is recording.**

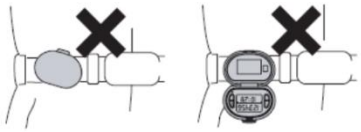
4) If the red light on the ActiGraph flashes at any time or if the elastic belt becomes loose / detaches from the ActiGraph, please call the research team. Their contact numbers are at the end of this instruction manual.

Using the Pedometer

Picture 3

1) You should wear the pedometer (see Picture 3) to the inside of the ActiGraph on the ActiGraph belt on the hip area of the waist on your dominant side (i.e. _____ side) (see Picture 2) **(Please note the device can be worn above or beneath clothing so does not have to be worn against the skin).**

2) Please make sure the monitor sits level on your waist and is not tilting forwards or to the side (see Picture 4).



Picture 4

Using the Activity Monitor Diary

1) Please start filling in the activity monitor diary after Visit 1.
2) Please use the activity monitor diary to record when you put on the activity monitors each morning and also the time you took off the activity monitors each night.
3) If you forget to wear any of the activity monitors, please write this down on the space provided on the activity monitor diary **(Write down which activity monitor you didn't wear, the times you didn't wear it and the reason why you didn't wear it).**

Contact details for the research team (REMOVED)

Activity Monitor Diary

	DATE	Time you put on the ActiGraph/ Pedometer	Time you took off the ActiGraph/ Pedometer	Amount of time and reason/s you didn't wear the monitor/s during the day
Example	*Sat 4th Feb*	*10.15am*	*11.30pm*	*8.00-10.15am (Forgot to put belt on when getting out of bed)*
Day of Visit 1				
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				
Day of Visit 2				

Activity monitors returned: Date_____ Time_____

***Please record the times to the nearest 5 minutes**

Reminder System

Rules for Reminder System

- One reminder method can be selected
- Remember to write which day the participant requests a reminder
- Participants can receive one reminder over the seven full days
- The time of the reminders must be between 08.00 – 12.00

Please tick the choice of reminder system/s:

Reminder Method	**When & time**
Patient selected reminder system	
Text/phone call/email	

Please tick if the participant **declines** any reminder system ❑

Next Appointment

Your next scheduled appointment is:

Visit 2 (+ 8 days after Visit 1): ____ / ____ / _____ at ____am/pm

APPENDIX 4

DATA CHECKING AND WEAR TIME COMBINATIONS FOR ACTIGRAPH AND PEDOMETER PRE ANALYSIS

Data checking and wear time combinations for ActiGraph and pedometer pre analysis

The analysis of the ActiGraph is a complex process with several stages, additionally there is little guidance regarding the wear time rules for the inclusion of data. Therefore to ensure high quality ActiGraph data, the data was checked and different wear time combinations were explored prior to analysis. The data entry for the pedometer as also checked in this process. The aim of conducting data checking and exploring different wear time combinations is to ensure high quality data and valid results.

Data checking was carried out by OO'S with JW. JW completed his PhD in Physical Activity in Patients with Bronchiectasis, and has experience in downloading and analysing ActiGraph data and managing pedometer data. Therefore as new information came to light throughout the analysis of our data we revised our data analysis process to ensure the maximal use of our data.

OO'S and JW met on two separate occasions in September and October 2015. On the first occasion, JW provided training to OO'S. OO'S processed 5 raw data baseline files and the corresponding 5 raw data post intervention files through the ActiLife 6.11.9 to ensure the process was accurate. On the second occasion JW observed OO'S processing 5 raw data follow up files (from the same participants) through the ActiLife software. The wear time for each of these files was explored against the documented wear time in the participants' diaries. For some participants there were large discrepancies between the diary and ActiLife output of wear time, it was decided to only include data that met the wear time criteria as reported in the ActiLife results. Wear time criteria at this time point was 5 days of ten hours of wear time (Gretebeck and Montoye 1992, Trost et al. 2005).

After the training and standardisation process, OO'S proceeded to analyse the ActiGraph activity. It became clear that a number of participants were not meeting the wear time criteria of 5 days of ten hours and that we would need to explore some more lenient wear time options. In January 2016, all data for the LIVELY COPD trial had been collected and OO'S attended an ActiGraph training course at Leicester-Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit (Measure 2016). The

facilitators of this course advised the wear time rules (days and weeks) should be flexible to allow available data to be maximised; advising that as little as one day and seven hours per day should be considered. Following this advice, the available pre-post data was considered a priority and a matrix determining the percentage of participants that had both pre and post data at each of the combinations of wear time was formulated (Table 2). There were 28 combinations from 7-10 hours and 1-7 days. Additionally in January 2016 Byron and Rowe published a review identifying the methodology used in the use of accelerometers to measure free living activity in patients with COPD; the authors recommend using a minimum of 5 days and 10 hours of wear time to describe activity in the COPD population (Byron and Rowe 2016). In March 2016, taking into account the results of the matrix and the recommendations by Byron and Rowe 2016, it was then decided to explore the ActiGraph data using three different combinations: 5 days of 7 hours wear time, 6 days of 7 hours wear time (where 92.9% (n=13) of available data sets in both groups met these criteria) and 5 days of ten hours wear time (85.7% (n=12) of available data sets from PAI and 78.6% (n=11) from the PR group met these criteria). OO'S and JW met in April 2017, to apply the new parameters for analysis. The data was processed for the baseline, post intervention and follow up data across all of these parameters. The corresponding pedometer data was added to the ActiLife Excel outputs; only pedometer data that recorded 100-50,000 steps per day was included (Matthiessen et al. 2015). JW cleaned the PAI pre-post data of 5 days of 7 hours wear time; OO'S checked these were correct. OO'S cleaned the remaining Excel files and JW checked these to make sure they were correct. Cleaning here refers to the process of ensuring that only data that meets the criteria is included and removing any additional data. All errors were rectified the data was copied into SPSS version 22.0 and analysed using descriptive statistics. The data (mean (standard deviation)) was tabulated for each combination of wear time, Table 2 Pre-post ActiGraph data across 4 days of 7 hours, 5 days of 7 hours and 5 days of 10 hours of wear time for the PAI group and Table 3 Pre-post ActiGraph data across 4 days of 7 hours, 5 days of 7 hours and 5 days of 10 hours of wear time for the PR group.

References

Byron B and Rowe DA., 2016. Measuring free-living physical activity in COPD patients: Deriving methodology standards for clinical trials through a review of research studies. Contemporary Clinical Trials; 47:172–184.

Gretebeck, R.J. and Montoye, H.J., 1992. Variability of some objective measures of physical activity.Medicine and Science in Sport and Exercise; 24(10):1167-72.

Matthiessen. J., Raustorp. A., Knudson. V., 2015. Reduction in pedometer-determined physical activity in the adult Danish population from 2007 to 2012. Scandinavian Journal of Public Health; 1–9.

Trost, S.G., McIver, K.L. and Pate, R.R., 2005. Conducting accelerometer-based activity assessments in field-based research. Med Sci Sports Exerc.; 37(11 Suppl):S531-43.

Appendix 4.Table 1 Matrix of the percentage of available Actigraph data for participants who have both pre and post data at each combination of wear time ranging between 7-10 hours s and 1-7 days for PAI group and the PR group

PAI percentage of participants with pre-post ActiGraph data by days and hours (N=14 total)							
Days / Hours	7	6	5	4	3	2	1
10	35.7%	64.3%	85.7%	85.7%	85.7%	92.9%	100%
9	50%	85.7%	85.7%	85.7%	85.7%	92.9%	100%
8	57.1%	85.7%	92.9%	92.9%	92.9%	100%	100%
7	78.5%	92.9%	92.9%	92.9%	92.9%	100%	100%
PR percentage of participants with pre-post ActiGraph data by days and hours (N=14 total)							
Days / Hours	7	6	5	4	3	2	1
10	64.3%	78.6%	78.6%	85.7%	85.7%	85.7%	92.9%
9	71.4%	78.6%	78.6%	85.7%	85.7%	92.9%	92.9%

8	78.6%	78.6%	85.7%	92.9%	92.9%	92.9%	92.9%
7	78.6%	92.9%	92.9%	92.9%	92.9%	92.9%	92.9%

Appendix 4, Table 2 Pre-post ActiGraph data across 4 days of 7 hours, 5 days of 7 hours and 5 days of 10 hours of wear time for the PAI group

PAI Group: 6 days of 7 hours wear time N=13	**BASELINE Mean (standard deviation)**	**POST INTERVENTION Mean (standard deviation)**
MVPA $_{10+}$ number of bouts	.0.659(0.138)	0.495 (1.118)
MVPA$_{10+}$ time (mins/day)	1.066 (2.181)	9.503 (21.480)
Total MVPA	17.014 (15.937)	22.982 (26.689)
ActiGraph steps	3714.199 (1996.251)	4598.7637
ActiGraph step category	Sedentary N=11 Low active N=1 Somewhat active N=1	Sedentary N=10 Low active N=1 Somewhat active N=1 Active N=1
Pedometer steps N=12	3604.492 (2037.442)	4974.206 (3638.158)
Pedometer step category	Sedentary N=9 Low active N=3	Sedentary N=9 Low active N=1 Active N=1 Highly active N=1
PAI Group: 5 days of 7 hours wear time N=13	**BASELINE Mean (standard deviation)**	**POST INTERVENTION Mean (standard deviation)**
MVPA $_{10+}$ number of bouts	0.209 (0.376)	0.495 (1.118)
MVPA$_{10+}$ time (mins/day)	1.253 (21.86)	9.503 (21.480)
Total MVPA	18.464 (15.477)	22.932 (26.718)
ActiGraph steps	3794.8040 (1986.284)	4657.764 (3080.644)
ActiGraph step category	Sedentary N=11 Low active N=1 Somewhat active N=1	Sedentary N=10 Low active N=1 Somewhat active N=1 Highly active N=1

Pedometer steps N=12	3564.026 (2038.213)	5137.694 (3537.681)
Pedometer step category	Sedentary N=9 Low active N=3	Sedentary N=8 Low active N=2 Somewhat active N=1 Active N=1 Highly active N=1
PAI group 5 days of 10 hours wear time N=12	**BASELINE Mean (standard deviation)**	**POST INTERVENTION Mean (standard deviation)**
MVPA $_{10+}$ number of bouts	0.0762 (0.146)	0.536 (1.158)
MVPA$_{10+}$ time (mins/day)	1.348 (2.399)	10.295 (22.236)
Total MVPA	17.519 (17.044)	24.171 (27.502)
ActiGraph steps	3766.246 (2092.008)	4738.264 (3219.081)
ActiGraph step category	Sedentary N=9 Low active N=2 Somewhat active N=1	Sedentary N=9 Low active N=1 Somewhat active N=1 Active N=1
Pedometer steps N=10	3671.321 (2221.798)	5325.946 (3923.210)
Pedometer step category	Sedentary N=7 Low active N=3	Sedentary N=6 Low active N=2 Highly active N=2

Appendix 4, Table 3 Pre-post Actigraph data across 4 days of 7 hours, 5 days of 7 hours and 5 days of 10 hours of wear time for the PR group

PR group 6 days of 7 hours wear time N=13	**BASELINE Mean (standard deviation)**	**POST INTERVENTION Mean (standard deviation)**
MVPA $_{10+}$ number of bouts	0.024 (0.083)	0.012 (0.412)
MVPA$_{10+}$ time (mins/day)	0.300 (1.041)	0.122 (0.423)
Total MVPA	6.594 (5.995)	6.524 (4.366)
ActiGraph steps	2620.845 (1620.363)	2595.542 (1379.456)
ActiGraph category	Sedentary N=11 Low active N=1	Sedentary N=12
Pedometer steps N=7	3475.857 (1955.451)	3216.422 (1978.525)

Pedomter step category	Sedentary N=6 Low active N=1	Sedentary N=5 Low active N=2
PR group 5 days of 7 hours wear time N=13	**BASELINE Mean (standard deviation)**	**POST INTERVENTION Mean (standard deviation)**
MVPA $_{10+}$ number of bouts	0.033 (0.0856)	0.011 (0.039)
MVPA$_{10+}$ time (mins/day)	0.459 (1.149)	0.113 (0.406)
Total MVPA	10.823 (16.293)	11.951 (19.379)
ActiGraph steps	3154.143 (2470.639)	3160.6187 (2424.307)
ActiGraph step category	Sedentary N=11 Low active N=1 Somewhat active N=1	Sedentary N=12 Somewhat active N=1
Pedometer steps N=8	3813.9464 (2047.429)	3756.694 (2385.475)
Pedometer step category	Sedentary N=6 Low active N=2	Sedentary N=5 Low active N=2 Somewhat active N=1
PR group 5 days of 10 hours wear time N=11	**BASELINE Mean (standard deviation)**	**POST INTERVENTION Mean (standard deviation)**
MVPA $_{10+}$ number of bouts	0.039 (0.092)	0.013 (0.431)
MVPA$_{10+}$ time (mins/day)	0.542 (1.238)	0.133 (0.442)
Total MVPA	12.552 (17.281)	13.408 (20.864)
ActiGraph steps	3624.201 (2411.091)	3628.460 (2356.804)
ActiGraph step category	Sedentary N=9 Low active N=1 Somewhat active N=1	Sedentary N=10 Somewhat N=1
Pedometer steps N=8	3824.241 (2032.852)	3733.439 (2384.497)
Pedometer step category	Sedentary N=6 Low active N=2	Sedentary N=6 Low active N=1 Somewhata active N=1

APPENDIX 6

LIST OF BEHAVIOUR CHANGE STRATEGIES INCLUDED IN THE LIVELY PHYSICAL ACITIVTY INTERVENTION (AMENDED)

Amended List of Behaviour Change Strategies included in the LIVELY PAI

LIVELY PAI Component
1. Setting an overall walking (or functional) goal e.g. walking to sisters house or walking into town every day as a results of the increased step counts/physical activity
2. Provide information on the consequences of behaviour in general and for the individual and (pro/cons) of being more active (any risks of not being more active)
3. Disease specific education.
4. Discuss barriers to physical activity
5. Training to use pedometer (including 20 step test) and completion of 7 day diary= skills/demonstration.
6. (a) Use pedometer steps in self-efficacy walk to set step goal (b) Use 7 day pedometer steps to set step goal
7. Build self-efficacy focusing the patient's attention on where they have been able to do well and focus on achievements.
8. Demonstrate appropriate walking pace during self-efficacy walk and Borg rating
9. Plan behaviour using action and coping plan
10. Record daily steps with pedometer
11. Review Smart goal
12. Review planned and actual walking behaviour each week with clinician by reviewing diary and pedometer daily step count and provide feedback
13. Review if goal met, not met or partially met
14. Reward success/effort
15. Certificate of achievement
16. Clinician encourages social support, walking with friends/family or walking to meet somebody etc.
17. Week 12 refer back, also review past success and also in terms of successful strategies.
18. Plan for relapse prevention
19. Materials manual i.e. LIVELY patient manual (includes diary) and LWWCOPD for PR

APPENDIX 8

TIDIER CHECKLIST RESULTS FOR THE CLINICIAN FACILITATED PHYSICAL ACTIVITY INTERVENTION VERSUS PULMONARY REHABILITATION IN IMPROVING PHYSICAL ACTIVITY IN COPD: A FEASIBILITY STUDY

Appendix 8: TIDieR Checklist Results for the Clinician facilitated physical activity intervention versus pulmonary rehabilitation in improving physical activity in COPD: A feasibility study

TIDieR Checklist	**Reported**
1.Brief name: provide a name or a phrase that describes the intervention	✓
2.Why: Describe any rationale theory or goal of elements essential to the intervention	✓
3. What (materials): describe any physical or informational materials used in the intervention including those provided to participants or used in the intervention or in training of intervention providers. Provide information on where the materials can be accessed (materials can be accessed by contacting b.oneill@ulster.ac.uk)	✓
4. What (procedures): describe each of the procedures, activities and or processes used in the intervention including any enabling or support activities.	✓
5. Who provided: for each category of intervention provider, describe their expertise background and specific training given.	✓
6. How: Describe the modes of delivery such as face to face or by some other mechanism, such as internet/telephone) of the intervention and whether it was provided individually or in a group.	✓
7. Where: Describe the type(s) of location(s) where the intervention occurred including any necessary infrastructure or relevant features	✓
8. When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule and their duration, intensity and dose	✓
9. Tailoring: If the intervention was planned to be personalised, titrated or adapted then describe what, why when and how	✓
10. Modifications: If the intervention was modified during the course of the study describe the changes (What, why, when and how)	N/A
11. How well (planned): if the intervention adherence or fidelity was assessed, describe how and by whom and if any strategies were used to maintain or improve fidelity describe them.	✓
12. How well (actual): If the intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	✓

APPENDIX 9

ETHICAL APPROVAL FROM THE NORTHERN IRELAND RESEARCH ETHICS COMMITTEE

HSC Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel: + 44 (0) 28 9260 3107
Fax: + 44 (0) 28 9260 3619
www.orecni.hscni.net

HSC REC 2

21 March 2013

Dr Brenda O'Neill
Lecturer in Physiotherapy
Room 01F119, Health and Rehabilitation Sciences Research Institute
University of Ulster, Jordanstown
Shore Road
Newtownabbey
Co Antrim
BT37 OQB

Dear Dr O'Neill

Study title: **Physical activity intervention versus pulmonary rehabilitation in COPD: the LIVELY COPD Project**
REC reference: **13/NI/0014**
IRAS project ID: **107423**

Thank you for your letter of 07 March 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Miss Jan Daley, jan.daley@hscni.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Other: NI CHS Research Grant Review		
Other: Response to UU Peer Review		
Participant Consent Form: Clean copy, tracked changes	2	07 March 2013
Participant Information Sheet: Clean copy, tracked changes	2	07 March 2013
Protocol	1	20 January 2013
Questionnaire: Marcus's Self-Efficacy	1	02 March 2012
Questionnaire: International Physical Activity		
Questionnaire: Health ED-5D-5L		
Questionnaire: COPD Assessment Test (CAT)		24 February 2012
Questionnaire: Stages of Change	1	02 March 2012
REC application	3.4	23 January 2013
Referees or other scientific critique report UU (RG1, RG2x2 & RG3		
Response to Request for Further Information		
Summary/Synopsis (Flowchart)	1	20 January 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/NI/0014 **Please quote this number on all correspondence**

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter Signed Dr Brenda O'Neill		20 January 2013
Covering Letter Dr B O'Neill		07 March 2013
GP/Consultant Information Sheets	1	20 January 2013
Investigator CV Dr Brenda O'Neill		20 January 2013
Letter from Sponsor UU		24 January 2013
Letter from Statistician Evie Gardner		20 November 2011
Letter of invitation to participant	1	20 January 2013
Other: Protocol for handling adverse events	1	20 January 2013
Other: Letter from Funder CHS		16 March 2012
Other: NI CHS Research Grant Application		

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

pp Jan Daley

Dr Ronald Atkinson
Chair

Email:jan.daley@hscni.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mr Nick Curry
Mrs Sally Doherty

HSC Business Services Organisation

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HSC REC B

23 April 2014

Dr Brenda O'Neill
Lecturer in Physiotherapy
University of Ulster
Room 01F119, Health and Rehabilitation Sciences Research Institute
University of Ulster, Jordanstown
Shore Road
Newtownabbey
Co Antrim
BT37 0QB

Dear Dr O'Neill

Study title:	**Physical activity intervention versus pulmonary rehabilitation in COPD: the LIVELY COPD Project**
REC reference:	**13/NI/0014**
Amendment number:	**Substantial Amendment #1**
Amendment date:	**21 March 2014**
IRAS project ID:	**107423**

The above amendment was reviewed at the meeting of the Sub-Committee held on 23 April 2014.

Ethical opinion

There were no ethical issues.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
LIVELY GROCPatient	Version 1	20 March 2014
LIVELY COPD Flowchart - Tracked	Version 2	20 March 2014
Notice of Substantial Amendment (non-CTIMPs)	Substantial Amendment #1	21 March 2014
LIVELY Protocol Adverse Event	Version 2	20 March 2014
Participant Consent Form: Informed Consent	Version 3	20 March 2014
Participant Information Sheet: PIS - LIVELY COPD - tracked	Version 3	20 March 2014
Protocol	Version 2 - Tracked	20 March 2014

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

13/NI/0014:	Please quote this number on all correspondence

Yours sincerely

Jane Keenan

PP
Professor Patrick Murphy
Chair

E-mail: jane.keenan@hscni.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mrs Sally Doherty*
Dr Brenda O'Neill, University of Ulster

HSC REC B

Attendance at Sub-Committee of the REC meeting on 23 April 2014

Name	*Profession*	*Capacity*
Mr John Edward Mone	Retired (Former Executive Director of Nursing)	Expert
Dr Sarah Anne Moorhead	Lecturer in Health & Interpersonal Communication	Lay

Also in attendance:

Name	*Position (or reason for attending)*
Miss Jane Keenan	REC Co-ordinator

Research Office

Notification of Amendment to a Research Project

HSC Belfast Health and Social Care Trust

Part 1- Project information			
Project Title	PhysicaL actIvity interVention vErsus puLmonarY rehabilitation in COPD: The LIVELY COPD Project.		
Research Office Ref:	12134BON-AS		
Date study originally commenced	1st Feb 2013		
Date of notification of amendment or extension	9th Sept 2014	Submitted by	Dr Brenda O'Neill

Part 2- Amendment / extension *(please select as appropriate)*			
Extension *(please go to part 3)*	No		
Amendment - Major *(please go to part 4)*	No	Amendment - Minor *(please go to part 4)*	Yes

(Please note if you are notifying of an extension and an amendment please fill in parts 3 &4)

Part 3- Extension information			
Original end date	N/A	Requested new end date	
Please detail reason for extension to project:			
Ethical extension for project required?	N/A	Date acquired *(please submit approval letter with this form)*	N/A

Part 4 – Amendment			
Amendment number	3	Amendment date	9th Sept 2014
Amendment to protocol	No	Amendment to information sheets/ consent forms or other supporting documents	No
Ethical approval required?	No	Date acquired *(please submit approval letter with this form)*	N/A
Please detail main changes proposed in this amendment. Explain the purpose of the changes and their significance to the study.			

Research Office

Notification of Amendment to a Research Project

HSC Belfast Health and Social Care Trust

(Additional information maybe attached)

Currently the LIVELY study is active in the WHSCT and BHSCT linking to pulmonary rehabilitation (PR) programmes within these Trusts.

Please add Miss Orlagh O'Shea to the LIVELY study research team. Orlagh is a physiotherapist and will commence her PhD which links to this study (registering at the University of Ulster on Oct 1st 2014). She will complete GCP training shortly and any specific Trust requirements and forward these in due course.

Orlagh will be fully embedded in this study and will link to research activities on the study including obtaining informed consent, confirmation of inclusion/exclusion with patients, conduct outcome assessment visits and patient interviews per study protocol, liaising with clinical PR teams, delivery of the physical activity intervention, data entry and analysis, study administration, and other relevant study related activities.

Part 5 – Trust support documentation		
Are there additional resources and/ or finances required?	No	If 'yes' please submit a new RAF form and, where applicable, additions to your Clinical Trial Agreement
Does this amendment/extension impact on other Trust Directorates?	No	If 'yes' please submit a new Protocol Impact Assessment form

Part 6 – Declaration

I confirm that the information in this form complete and accurate.
Sign:

Brenda O'Neill

Print: Brenda O'Neill

Date: 9th Sept 2014

Part 7 – Authorisation

I authorise the approval of this projects extension/ amendment as documented in the information provided

Name: _____

Position: _____

Date:

APPENDIX 10

STUDY APPROVAL FROM THE BHSCT GOVERNANCE SECTION

Belfast Health and Social Care Trust

04/07/2013

Dr Brenda O'Neill
Lecturer in Physiotherapy
Room 01F119, Health and Rehabilitation Sciences Research Institute
University of Ulster, Jordanstown
Shore Road
Newtownabbey
Co Antrim
BT37 0QB

Dear Dr O'Neill

Study Title: Physical activity intervention versus pulmonary rehabilitation in COPD: the LIVELY COPD Project

HSC Trust Ref: 12134BO'N-AS (Please quote this in all future correspondence)

REC Ref: 13/NI/0014

I am pleased to advise that Belfast HSC Trust has given final Research Governance Permission for the above project to commence. Permission is granted for the duration of the project to 28/02/15.

The following documents have been approved for use in the project:

Document	Version	Date
GP/Consultant Information Sheets	1	20 January 2013
Letter of invitation to participant	1	20 January 2013
Other: Protocol for handling adverse events	1	20 January 2013
Participant Consent Form	2	07 March 2013
Participant Information Sheet	2	07 March 2013
Protocol	1	20 January 2013
Questionnaire: Marcus's Self-Efficacy	1	02 March 2012
Questionnaire: International Physical Activity		
Questionnaire: Health ED-5D-5L		
Questionnaire: COPD Assessment Test (CAT)		24 February 2012
Questionnaire: Stages of Change	1	02 March 2012
Summary/ Synopsis (Flowchart)	1	20 January 2013

The following personnel have been approved to work on the study at this Trust:

Name	Indemnity Provided by
Dr Lorcan McGarvey	BHSCT
Dr Brenda O'Neill	UU
Prof Judy Bradley	BHSCT
Dr Adele Boyd	UU
Dr Denise Cosgrove	BHSCT

Permission is granted subject to the attached conditions and I would ask you to please ensure that all members of the research team are familiar with these. Failure to abide by these conditions will invalidate permission and may result in the cessation of the research.

I wish you every success with your project.

Yours sincerely,

Professor Ian Young
R&D Director

Cc
Dr Lorcan McGarvey
Dr Denise Cosgrove
Karen Hodgen

termination of the project. Completion reports must be sent to the Research Office, Research Ethics Committee and, if applicable, MHRA.

Conditions of Permission

Research Governance permission is issued provided the researcher(s) involved adhere to and abide by the conditions below.

- The researcher(s) must adhere strictly to the research protocol.
- There must be no changes to the research protocol or approved study documentation without the prior consent of the Trust, the Research Ethics Committee and, where applicable, the MHRA.
- There must be no changes in research staff without prior consent of the Trust.
- The Research Office should be informed if the Chief Investigator or Principal Investigator(CI/PI) is unable to continue to fulfil his/her duties as CI/PI for any reason such as long term absence, change in employment etc.
- There must be no increase in the resources required without prior consent of the Trust.
- Researcher(s) must report all untoward incidents and serious adverse events to the Trust.
- Any concerns in relation to the research protocol must be reported to the Trust.
- Researcher(s) must adhere to good research practice principles in line with the ICH Good Clinical Practice (GCP) guidelines.
- Researcher(s) must adhere to the Trust's Research & Development Standard Operating Procedures (available from the Research Office on request)
- On request, researcher(s) must make their research project available to Trust appointed monitors.
- The lead researcher must make an annual report to the Research Office for the duration of the project.
- The lead researcher should inform the Research Office on completion or termination of the project. Completion reports must be sent to the Research Office, Research Ethics Committee and, if applicable, MHRA.

APPENDIX 11

STUDY APPROVAL FROM THE WHSCT GOVERNANCE SECTION

Western Health and Social Care Trust

21 May 2013

Dr Brenda O'Neill
Senior Lecturer in Physiotherapy
University of Ulster
Room 01F119, CHaRT
Shore Road
Newtownabbey
Co Antrim
BT37 0QB

Dear Dr O'Neill

Study Title: Physical activity intervention versus pulmonary rehabilitation in COPD; the LIVELY COPD project

HSC Trust Ref: WT 12/20 107423 (Please quote this number in all future correspondence)

REC Ref: 13/NI/0014

I am pleased to advise that WHSCT has given Final Research Governance Permission for the above project to commence. Permission is granted for the duration of the project to 28/02/15.

The following documents have been approved for use in the project:

Document	Version	Date
Flowchart of study	V1 20/01/13	11/02/13
Protocol	V1 20/01/13	11/02/13
Protocol for handling adverse events	V1 20/01/13	05/04/13
Participant Invitation Letter	V1 20/01/13	11/02/13
Participant Information Sheet (clean and tracked)	V2 07/03/13	29/03/13
Informed Consent Form (clean and tracked)	V2 07/03/13	29/03/13
Information for GP/Referring Clinician	V1 20/01/13	11/02/13

Research & Development Office, C-TRIC, Altnagelvin Area Hospital, Londonderry BT47 6SB
DDI 02871 611156
02871 345171 EXT 216603/4

Western Health and Social Care Trust

Cc Mr Nick Curry, Research Governance, University of Ulster, Jordanstown
Dr Terence McManus, Consultant Physician, SWAH
Ms Alison Murphy, Research Manager, Belfast H&SC Trust

Conditions of Permission

Research Governance permission is issued provided the researcher(s) involved adhere to and abide by the conditions below.

- The researcher(s) must adhere strictly to the research protocol.
- There must be no changes to the research protocol or approved study documentation without the prior consent of the Trust, the Research Ethics Committee and, where applicable, the MHRA.
- There must be no changes in research staff without prior consent of the Trust.
- The Research Office should be informed if the Chief Investigator or Principal Investigator(CI/PI) is unable to continue to fulfil his/her duties as CI/PI for any reason such as long term absence, change in employment etc.
- There must be no increase in the resources required without prior consent of the Trust.
- Researcher(s) must report all untoward incidents and serious adverse events to the Trust.
- Any concerns in relation to the research protocol must be reported to the Trust.
- Researcher(s) must adhere to good research practice principles in line with the ICH Good Clinical Practice (GCP) guidelines.
- Researcher(s) must adhere to the Trust's Research & Development Standard Operating Procedures (available from the Research Office on request)
- On request, researcher(s) must make their research project available to Trust appointed monitors.
- The lead researcher must make an annual report to the Research Office for the duration of the project.
- The lead researcher should inform the Research Office on completion or termination of the project. Completion reports must be sent to the Research Office, Research Ethics Committee and, if applicable, MHRA.

Research & Development Office, C-TRIC, Altnagelvin Area Hospital, Londonderry BT47 6SB
DDI 02871 611156
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APPENDIX 12

ADDITIONAL BASELINE CHARACTERISITCS OF PARTICIPANTS IN THE LIVELY COPD PROJECT

Appendix 12, Table 1 Additional baseline characteristics for participants in the LIVELY COPD project

Baseline Demographic Characteristics	**Whole population N=50**	**Physical Activity Intervention N=23**	**Pulmonary Rehabilitation N=27**
Previous PR attendance			
(Frequency)	11	4	7
Yes	38	19	19
No	1	0	1
Missing			
SOC Questionnaire *(frequency)*			
Stage 1	0	0	0
Stage 2	18	6	12
Stage 3	18	10	8
Stage 4	4	2	2
Stage 5	10	5	5
Decisional balance			
Benefits of PA			
-Improved symptoms/respiratory health	24	11	13
-Improved mood/mental well being	14	5	9
-Weight control	8	3	5
-Increased activity/ be more active	7	4	3
-Improved general health and well being	20	9	11
-Social benefits	4	3	1
-Physical health benefits	16	7	9
-Increased confidence	4	1	3
-None			
-Other*	2	0	2
Downsides of PA	4	3	1
-Breathlessness			
-Fatigue	12	7	5
-Too much effort	1	0	1
-Frustration	2	1	1
-Time	3	2	1
-Finance	2	2	0
-Pain	1	1	0
-Comorbidities	2	2	0
-Being around people	1	1	0
-None	1	1	0
	29	11	18

SOC –Stages of Change

Regularly physically active relates to: Exercise e.g. weight training, aerobics for 20 minutes 3 times per week, OR Sport e.g. golf, hockey, netball, athletics, swimming for 20 minutes 3 times per week, OR General e.g. walking, cutting the grass, vacuuming, washing the car accumulating to at least 30 minutes 5 times per week.

SOC Questionnaire: Stage 1 - I am not regularly PA and do not intend to be so in the next 6 months; Stage 2 - I am not regularly PA but am thinking about starting to do so in the next 6

months; Stage 3-I do some PA but not enough to meet the description of regularly PA given above; Stage 4 -I am regularly PA but only began in the last 6 months; Stage 5 -I am regularly PA and have been for longer than 6 months.
*other refers to: improved self-discipline to control pace of walking; sleep pattern; enjoyment; to motivate me mentally.

APPENDIX 13

Baseline, post intervention and follow up outcome measure data for participants in the LIVELY COPD project

Appendix 13, Table 1 Baseline, post intervention and follow up outcome measure data for participants in the LIVELY COPD project

Outcome measure	Baseline PAI (n=23)	Baseline PR (n=27)	Post PAI (n=18)	Post PR (n=19)	Follow up PAI (n=15)	Follow up PR (n=18
ActiGraph	**N=17(*n =3,Σn=1, ®n=2)**	**N=24 (*n=3)**	**N=14(*n= 2,®n=1,Σ n=1)**	**N=12 (*n=2, ,®n=3, Σn=1, βn=1)**	**N=12 (*n=2, πn=1)**	**N=14 (*n=4)**
Step count	3305.6 (1960.2)	3946.2 (2263.1)	4768.2 (2992.1)	3476.6 (2307.9)	5332.0 (3070.7)	4984.6 (3598.0)
Total MVPA time (mins/day)	14.3 (15.3)	14.6 (15.3)	24.49 (26.0)	12.80 (20.0)	30.56 (26.4)	17.5 (26.6)
MVPA $_{10+}$ number of bouts	0.05 (0.1)	0.1 (0.2)	0.57 (1.1)	0.01 (0.04)	0.68 (1.0)	0.1 (0.3)
MVPA$_{10+}$ time (mins/day)	0.87 (2.0)	1.3 (3.0)	11.67 (21.5)	0.1 (0.4)	12.1 (29.6)	4.7 (16.3)
PA category sedentary	N=14	N=17	N=10	N=11	N=6	N=9
PA category Low active	N=2	N=5	N=2	N=0	N=3	N=2
PA category somewhat active & above	N=1	N=2	N=2	N=1	N=3	N=3
Pedometer	**N=22 (Σn=1)** 3044.4 (1871.1)	**N=21 (*n=6)** 3387.2 (1942.8)	**N=16 (*n=1, π n=1)** 5570.7 (3486.7)	**N=13 (*n=5, π n=1)** 3917.5 (2194.9)	**N=10(*n= 4, π n=1)** 5144.1 (3330.4)	**N=13 (*n=5)** 3496.6 (2869.0)
IPAQ Total PA level (MET/ mins/week)	1464.1 (1553.3)	1734.0 (1692.6)	2427.7 (1559.7)	**N=18 (Σ n=1)** 2229.9 (2189.9)	2294.2 (2157.3)	**N=17 (α n=1)** 2410.0 (2620.9)
IPAQ category score – Low	8	10	2	7	3	5

IPAQ category score Moderate	13	10	11	7	8	7
IPAQ category score – High	2	7	5	4	4	5
GROC *Worse* *Better* *No Change* *N/A*			**N=13 (αn=1, #n=4)** 1 12 0 0	**N=13 (αn1, #n=5)** 2 8 2 1	**N=11 (#n=4)** 1 7 3 0	**N=9(α n=1, #n=8)** 0 5 4 0
ISWT Distance (M)	253.0 (118.8)	254.81 (139.8)	**N=16 (α n=1, π n=1)** 288.1 (107.0)	**N=17 α (n=1, π n=1, **n=1)** 280 (139.7)	**N=14 (π n=1)** 302.1 (122.7)	**N=17 (α n=1,** 16.4 (7.6)
CAT	23.8(6.9)	19.4 (8.0)	**N=17 (Ω n=1)** 22.5 (7.0)	16.6 (5.3)	20.5 (9.3)	16.4 (7.6)
EQ-5D Weighted Health Index	0.5 (0.2)	0.6 (0.3)	0.5 (0.3)	0.7 (0.2)	0.5 (.3)	**N=17(α n=1)** 0.7 (0.2)
EQ5D Health state VAS	56.2 (20.8)	61.0 (18.9)	58.6 (23.0)	74.0 (19.9)	64.1 (17.6)	**N=17(αn= 1)**72.1 (15.4)
Marcus Self-efficacy	2.4 (0.7)	2.4 (0.8)	**N=17 (αn=1)** 2.9 (0.9)	**N=18(αn= 1)** 2.7 (0.6)	**N=14(αn= 1)** 3.1 (0.8)	**N=17(αn= 1)** 2.9 (0.8)

MVPA- Moderate to Vigorous Physical Activity
IPAQ- International Physical Activity Questionnaire
GROC- Global Rating of Change
ISWT- Incremental Shuttle Walk Test
CAT-COPD Assessment Test
*Not meeting criteria (ActiGraph: 5 days of ten hours wear time, pedometer: 100-50,000 steps recorded) Σ patient non-compliant with wearing device ® researcher download error.π: paper based outcomes only completed. β ActiGraph error, α: unable/unwilling to complete, # outcome measure added to CRF post visit Ω Outcome measure not available in CRF, α: unable to complete as unwell and unable to travel, **n=1 outliers

APPENDIX 14

STANDARD OPERATING PROCEDURE FOR INITIALISING, DOWNLOADING AND ANALYSING ACTIGRAPH

Appendix 14: Standard operating procedure for initialising, downloading and analysing Actigraph

Complete this table for each participant in the study

Study title: _____

Participant number: _____

Visit number: _____ Date of visit: _____

Activity	Date	Completed by
Initiate Actigraph Date from: ___/___/_____ Date to: ___/____/_____	___/___/_____	
Collect Actigraph from patient	___/___/_____	
Download Actigraph data Location:_____	___/___/_____	
Analyse Actigraph data	___/___/_____	
Analysis of Actigraph data, checked by second person.	___/___/_____	
Activity data from ___/___/_____ To ___/___/_____		
Patient meeting wear time criteria (5 days of 10 hours per day)	Yes ☐ No ☐ Comment:	

APPENDIX 16

QUALITATIVE RESEARCH TEAM: CREDENTIALS, TRAINING AND/OR EXPERIENCE

Appendix 16 Table 1: Qualitative analysis research team: credentials, training and/or experience

	Credentials	Training/experience
Orlagh O'Shea	-BSc Physiotherapy -MSc Exercise Physiology -PhD student: 'Physical Activity in people with COPD.'	-Essentials of Qualitative Research (Prof Brian Taylor, 19/11/14) -Practical Qualitative Research Skills Workshop (Dr Iseult Wilson, 15/06/15) at Ulster University. -Fundamentals of Qualitative Data Analysis (Dr Jane Forman 05/05/15) -Writing with Qualitative Data (Prof Jennifer Mason 06/05/15) at Dublin City University Qualitative Summer School.
Professor Judy Bradley	-BSc Physiotherapy, -PhD 'The assessment of disability and handicap in adult Cystic Fibrosis'	-Experience with pharmacological and non-pharmacological qualitative and quantitative trials.
Dr Brenda O'Neill	-BSc Physiotherapy, -PhD 'The efficacy and use of ambulatory and short burst oxygen therapy in Chronic Obstructive Pulmonary Disease'	-Experience with rehabilitation trials, both qualitative and quantitative in the COPD and other respiratory populations.
Dr Adele Boyd	-BSc Biomedical Science -PhD	-Training with LIVELY COPD project team to conduct semi structured interviews.
Professor Madelynne Arden	-BSc Psychology -PhD	-Experience in behaviour change research for different health behaviours and in the conduct of qualitative and quantitative trials.
Natasha Green	-BSc Sport Science -MSc Sport and Exercise Science and Medicine -PhD student: 'Physical function and activity in survivors of critical illness following discharge from the intensive care unit'	-Informal training with King's Template Anlaysis; A method of analysing interview transcripts in qualitative research from JB and OO'S
Alanna Rogan	-BSc Physiotherapy - PhD student: 'Physical function and activity in survivors of critical illness following discharge from the intensive care unit'	-Informal training with King's Template analysis; A method of analysing interview transcripts in qualitative research from JB and OO'S

APPENDIX 17

A PRIORI THEMES FOR QUALITATIVE COMPONENT OF THE LIVELY COPD PROJECT

A priori themes for qualitative component

1. Benefit and impact of PAI/PR on health
   1.1 Physical health
   1.2 Mental health
   1.3 Social aspect
   1.4 Family noticing a difference in health/functional ability

2. Views and satisfaction with PAI/PR
   2.1 Content (how was this tailored to the individual's needs)
   2.2 Frequency of contact
   2.3 Information provided (education)
   2.4 Materials: LWWCOPD booklet (common); pedometer and step diary (PAI specific); Home exercise programme (HEP) (PR specific)
   2.5 Suggestions for improvement
   2.6 PAI specific: goal setting; reward; mode of contact

3. Adherence to the PAI/PR
   3.1 Facilitators for adherence to the PAI/PR
   3.2 Barriers to adherence to the PAI/PR

4. Views about the outcome measures
   4.1 Recommendations for the best method to test the effectiveness of the programme
   4.2 Questionnaires
   4.3 Activity monitors (two worn on belt)
   4.4 ISWT

5. Views about continuing exercise
   5.1 Plans for continuing exercise
   5.2 Facilitators to help participants to continue
   5.3 Motivation to continue

APPENDIX 18 INITIAL TEMPLATE FOR QUALITATIVE COMPONENT OF THE LIVELY COPD PROJECT

Initial template for qualitative component following analysis of 25% of transcripts from each group

1. **Benefit and impact of PAI/PR on health**
   - 1.1 Overall health
   - 1.2 Social activity and social support
   - 1.3 Enjoyment
2. **Views and satisfaction with PAI/PR**
   - 2.1 Content (how was this tailored to the individual's needs)
   - 2.2 Duration and frequency and mode of contact
   - 2.3 Information provided (education)
   - 2.4 Materials: LWWCOPD booklet (common); pedometer and step diary (PAI specific); Home exercise programme (HEP) (PR specific)
   - 2.5 Suggestions for improvement
   - 2.6 PAI specific: goal setting; reward
3. **Adherence to the PAI/PR**
   - 3.1 Facilitators for adherence to the PAI/PR
     - 3.1.1 Motivation
     - 3.1.2 Staff/providers
     - 3.1.3 Social support
     - 3.1.4 Pedometer
     - 3.1.5 Action and coping planning
     - 3.1.6 Individual strategies to increase PA
     - 3.1.7 Group setting
   - 3.2 Barriers to adherence to the PAI/PR
     - 3.2.1 Overall health
     - 3.2.2 Weather/environmental
     - 3.2.3 Social support
     - 3.2.4 Time/other commitments
     - 3.2.5 Group setting
     - 3.2.6 Motivation
4. **Views about the outcome measures**
   - 4.1 Recommendations for the best method to test the effectiveness of the programme
   - 4.2 Questionnaires
   - 4.3 Activity monitors (two worn on belt)
   - 4.4 ISWT
5. **Views about continuing exercise**
   - 5.1 Plans for continuing exercise
   - 5.2 Motivation to continue
   - 5.3 Confidence to continue

APPENDIX 19

AMENDED INITIAL TEMPLATE FOR QUALITATIVE COMPONENT OF THE LIVELY COPD PROJECT

Amended initial template for qualitative component following analysis of 25% of transcripts from each group

1. **Benefit and impact of PAI/PR on health**
   - 1.1 Overall health
   - 1.2 Social activity and social support
   - 1.3 Enjoyment
2. **Views and satisfaction with PAI/PR**
   - 2.1 Tailoring of content to the PAI/PR to the individual
   - 2.2 Frequency, duration and mode of contact with interventionist or provider
   - 2.3 Education and educational materials
   - 2.4 Suggestions for improvement
3. **Adherence to the PAI/PR**
   - 3.1 Facilitators for adherence to the PAI/PR
     - 3.1.1 Motivation
     - 3.1.2 Staff/providers
     - 3.1.3 Social support
     - 3.1.4 Pedometer
     - 3.1.5 Action and coping planning
     - 3.1.6 Individual strategies to increase PA
     - 3.1.7 Group setting
   - 3.2 Barriers to adherence to the PAI/PR
     - 3.2.1 Overall health
     - 3.2.2 Weather/environmental factors
     - 3.2.3 Social support
     - 3.2.4 Time/other commitments
     - 3.2.5 Group setting
     - 3.2.6 Motivation to do programme independently
4. **Views about the outcome measures**
   - 4.1 Recommendations for the best method to test the effectiveness of the programme
   - 4.2 Questionnaires
   - 4.3 Activity monitors (two worn on belt)
   - 4.4 ISWT
5. **Views about continuing exercise**
   - 5.1 Plans for continuing exercise
   - 5.2 Motivation to continue
   - 5.3 Confidence to continue

APPENDIX 20

FINAL TEMPLATE FOR QUALITATIVE COMPONENT OF THE LIVELY COPD PROJECT

Final Template for Qualitative Component (following verification by colleagues)

1. **Perceived benefit and impact of PAI/PR**
   - 1.1 Physical health
   - 1.2 Mental health
   - 1.3 Social activity and social support
   - 1.4 Enjoyment
2. **Views of and satisfaction with PAI/PR**
   - 2.1 Tailoring of the content of the PAI/PR to the individual
   - 2.2 Frequency, duration and mode of contact with interventionist or PR staff
   - 2.3 Education and education materials
   - 2.4 Suggestions for improvement
3. **Adherence to the PAI/PR**
   - 3.1 Facilitators for adherence to the PAI/PR
     - 3.1.1 Intrinsic motivation
     - 3.1.2 Staff/interventionists
     - 3.1.3 Social support
     - 3.1.4 Pedometer and action and coping planning (PAI specific)
     - 3.1.5 Individual strategies to increase PA (PAI specific)
     - 3.1.6 Group setting (PR specific)
   - 3.2 Barriers to adherence to the PAI/PR
     - 3.2.1 Physical health
     - 3.2.2 Mental health
     - 3.2.3 Weather/environmental factors
     - 3.2.4 Lack of social support
     - 3.2.5 Time/other commitments
     - 3.2.6 Group setting (PR specific)
     - 3.2.7 Motivation to do programme independently (PR specific)
4. **Views about the outcome measures**
   - 4.1 Activity monitors (two worn on belt)
   - 4.2 ISWT
   - 4.3 Questionnaires
   - 4.4 Recommendations for the best method to test the effectiveness of the programme
5. **Views about continuing exercise/PA**
   - 5.1 Plans for continuing exercise/PA
   - 5.2 Motivation and confidence to continue exercise/PA

APPENDIX 21

CHARACTERISTICS AND REFERENCES FOR INCLUDED PAPERS IN THE FIDELITY REVIEW: A SCOPING REVIEW OF THE METHODSUSED TO EVALUATE TREATMENT FIDELITY IN BEHAVIOURAL CHANGE INTERVENTIONS

Appendix 21 Table 1 characteristics and references for included papers in the fidelity review: a scoping review of the methodsused to evaluate treatment fidelity in behavioural change interventions

Author and study design	Aims/objectives	Population	Intervention (n=) control (n=)	Definition/description of fidelity	Methods of assessing fidelity
Bailey and Blair 2015[1S] Design: A multiple-baseline design	To examine the feasibility and outcomes of implementing the family-centred prevent teach reinforce model by replicating Sears et al. in a new sample.	Children with developmental disorders	N=3 boys aged 5-7	No definition.	♦All sessions were audio recorded. ♦Implementation fidelity was assessed using a specific checklist; which focused on the number of steps which were correctly implemented.
Beck et. al 2015[2S] Design: Study protocol for a step wedged randomised control trial.	To describe the methodology for promoting and facilitating the evaluation of intervention fidelity in The EAT (Eating As Treatment) project.	Patients undergoing radiotherapy for head and neck cancer.	Not reported; recruitment on-going	Treatment fidelity encompasses strategies designed to monitor and enhance the reliability and validity of behavioural interventions (Borrelli et al. 2005a).	♦**Study design:** Stated the underpinning theories and how these impacted the active components and the overall design of the study. The exact dose could not be set out given the flexibility of the designed intervention; providers completed a log and audio recorded sessions to verify this. Strategies were used to minimise contamination between groups (keeping providers blind to the intervention content during the control period and told not to discuss details of their intervention beyond their site, any apparent contamination will be analysed from audio recordings), the study team also provided for possible setbacks by training more providers than necessary and tailoring the training content and schedule to suit the providers.

					♦**Provider training**: training was standardised for all providers as it was conducted by the same trainers using the same powerpoints, role play and discussions were used to ensure that the training was suited to the individual needs. Skill acquisition was assessed by self report assessments done before and after training, role plays were also videoed to assess skill acquisition. Ongoing supervision and feedback was provided to measure competence in delivering the intervention. Any concerns regarding clinician delivery of the intervention are discussed with the research team and raised with the clinician. This on-going supervision helped minimise drift in provider skills in addition to summarising key concepts on supplementary resources to prompt integration of training concepts into clinical practice. Booster training sessions were also completed. ♦**Delivery:** Supervision was used to monitor delivery. All sessions were audio recorded and assessed using an intervention specific checklist and standardised checklists to assess delviery. 20% of audio recorded were randomly seleted for assessment by trainined raters Providers had to score a minimum level on these checklists, if there were any concerns regarding delivery they were raised with the study team. Questionniares were used to collect information about the proviers previous training and clincal experience to account for any difference in providers; other questionnaires were used to assess dietician and patient perception of

					therapeutic alliance and the providers interpersonal skills were also measured. ♦**Receipt:** The authors felt that it was difficult to adopt the concept of receipt for this particular intervention and their interpretation of receipt for this was to focus on the degree to which the intervention was delivered.
Casey et. al 2015[3S] Design: Multiple baseline single-subject design	To evaluate the effects of a highly structured therapeutic skating intervention on motor outcomes and functional capacity.	Boys with autism spectrum disorder aged 7 and 10 years	Intervention n=2	No definition	♦Recorded attendance at specific time points. ♦At a particular time point specific measurements were taken of the tasks to be completed in the two trials.
Chesworth et. al 2015[4S] Design: *A priori* method of assessing fidelity of a Cluster randomised feasibility trial.	To explore fidelity to treatment delivery of the ICONS (Identifying Continence OptioNs after Stroke) intervention.	Adults post stroke	Intervention (n=40). Control (n=31)	"…the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions…[and] …the methodological practices used to ensure that a research study reliably and validly tests a clinical intervention" (Bellg et al. 2004)	♦Clinical logs completed by the providers regarding the delivery of the intervention were reviewed.

Fortington et. al 2014[5S] Design: Observational	To measure the quality of exercise performance by players in FootyFirst, a coach-led, lower-limb injury prevention program.	Australian football players	Observed n=70	The extent to which a programme is followed as prescribed and adaptation is the extent to which a program is changed after implementation in a real world setting Hansen 2013, Allen et al. 2012).	♦Players were observed carrying out the exercises by two raters using a specifically designed checklist. Only observations that the raters agreed on were used for analysis.
French et. al 2015[6S] Design: Comparison of planned and actual and observed versus self-assessed BCTs during the intervention.	To evaluate the fidelity of the IMPLEMENT intervention ; an interactive face-to-face educational intervention to improve general practitioner (GP) management of back pain	General practitioners	Intervention (n=59) Control (n=53)	Intervention fidelity refers to both the methodological strategies used to monitor and enhance the reliability and validity of delivery of interventions, and the extent to which an intervention as delivered is faithful to the intervention as planned (Bellg et al. 2004, Borrelli et al. 2005).	♦All workshop sessions were audio recorded and transcribed. The audio recordings were coded according to the presence of behavioural change techniques (BCTs). To establish reliability one transcript was coded by two raters and an agreement of 80% for the presence of a BCT had to be reached. One of these raters then coded the remaining transcripts 10% of which were randomly checked.
Fulkerson et. al 2015[7S] Design: Randomised control trial	To describe weight-related outcomes of the Healthy Home Offerings via the mealtime environment Plus	Families (8-12 year old children and their parents)	Intervention (n=81) Control (n=79)	No definition	♦Pre-selected sessions were observed and delivery assessed using a standardised checklist.

	study; a trial to prevent excess weight gain among youth.				
Hanbury et. al 2015[8S] Design: Assessment of fidelity of an educational workshop	To summarise the fidelity assessment of a workshop designed to increase the uptake of a primary care alcohol screening recommendation.	Healthcare practitioners (general practitioners (GP), nurses, specialist alcohol service workers, healthcare assistants, dentists, health trainers)	N=62 participants (n=32 GPs, n=11nurses , n=4 specialist alcohol service workers, n=4 healthcare assistants, n=2 dentists, n=9 health trainers)	How well the delivery and receipt of the intervention mirrors the plans of those who have developed it – the intervention's fidelity – is increasingly recognised as an important determinant of its effectiveness. (No reference)	♦Sessions were observed and delivery assessed using a specified fidelity checklist, which rated the providers' adherence to the protocol. The providers' presentations were also examined for adherence and their presentation skills also rated. ♦Participant feedback regarding the style of the providers' delivery and the quality of the intervention was obtained. ♦Exposure/dose was evaluated by examining the attendance records to assess the number of targeted health professionals attending and the number of practices with representation.
Lawton et. al 2015[9S] Design: Fidelity analysis of a large matched-pair cluster randomised controlled trial	To test whether the effectiveness of a worksite physical activity intervention delivered in five work organizations varied as a function of fidelity.	Employees from 5 organisations across the UK (local council, hospital, bus company, government organisation, university)	N=1260	It is now widely acknowledged that when testing complex interventions via randomized controlled trials, it is important to collect data about how the intervention is delivered in practice (fidelity) and whether this varies according to the	♦ (1)Adherence: assessed the extent to which each of the facilitators had delivered each of the 9 components. ♦ (2) Quaility of delivery was assessed self-report: facilitators were asked a number of questions regarding their perceptions of the quaility of the delivery and facilitators also reported on the number of hours they spent implementing the intervention. ♦ (3) Exposure: participants had to indicate the extent to which they had received each of the 9 components (yes/no) ♦ (4) Responsiveness was measured by exploring participants' perceptions of

				context (Bellg et al. 2004, Oakley et al. 2006, Craig et al 2008).	usefulness of each of the components of the intervention. ♦ (5) Engagement: particpants were asked to indicate whether they had taken part in the team challenges. Scores across all 4 domains was used to evaluate fidelity.
Martin et. al 2015 [10S] Design: A quasi experimental, pretest/ posttest design was used	To develop a sustainable, skill-based training program to assist older adults with their medication management	Community-dwelling older adults.	N=198	No definition	♦Academic research staff assisted with the development of a programme manual ♦Academic research staff attended all initial sessions delivered at each site to assess fidelity to the programme and materials and provided. Feedback was also provided.
McNamara et. al 2015[11S] Design: A single-cohort intervention study	To determine intervention fidelity by pharmacists for behavioural components of a complex educational intervention for cardiovascular disease (CVD) prevention.	Patients without established CVD, taking anti-hypertensive or lipid lowering therapy aged 50-74.	N=70	Demonstrable intervention fidelity is an important component of verifying a cause–effect relationship within complex intervention studies (Craig et al. 2008).	♦ (1)Process indicators examined the appropriatess and suitability of the structure (taken from provider documentation); retention of participants and time taken to deliver the intervention. ♦ (2)Prcoess indicators were used to determine the appropriatene targetting and delivery of the intervention; (i) recruitment of particpants with uncontrolled risk factors (baseline documentation). (ii) Recommendations of goals to address particpants risk factors (baseline documentation). (iii) Patient agreement to pursue recommendations of strategies (taken from provider documentation). (iv) Development of strategies to address risk factors/goals (taken from provider

					documentation). (v) Indentification of barriers and enablers to behaviour change inititaion and maintenance (taken from provider documentation). ♦Providers also documetned their percieved success of behaviour strategies. ♦Self assessed perceived competence by providers to deliver the intervention was documented. ♦Providers perceived need for further patient support at completion of the intervention was documented.
Pawar et. al 2015[12S] Design: Cluster randomised control trial	To examine the feasibility of delivering an intervention promoting tobacco use cessation among school teachers.	School teachers	N=72 schools (n=36 control and n=36 intervention)	The extent to which intervention was delivered as planned ('fidelity'). (No reference)	♦Points were awarded if an inte component was implemented, t higher the score obtained the higher the fidelity.
Pincus et. al 2015[13S] Design: Randomised controlled feasibility trial	To test the credibility and acceptability of offering contextual cognitive behavioural therapy (CCBT) to patients with high fear avoidance who had been referred to physiotherapy.	Avoidant low back pain patients	N=89 (n=45 intervention, n=44 control)	No definition	♦The delivery of CBBT was assessed from audio recordigns using a structured coding format. ♦The fidelity of the physiotherapists was established through (1) Exit interviews with a sample of particpants (2) observations of one sessions per site the research team (3) exploration of the physiotherapy self report of session rating forms which detailed the components covered in each session.

Williams et. al 2015[14S] Design: Cluster randomised control trial	To investigate the role of Theory Planned Behaviour variables in predicting intention and objective walking behaviour in a sedentary general practice (GP) population.	Patients of GP practices aged 16-65 with one/more chronic condition, which increasing physical activity (PA) would have a positive effect and were sedentary (not meeting PA guidelines)	N=315 (n=136 intervention and n=179 control)	No definition	♦Providers were observed delivering the intervention before the trial commenced and were required to reach a minimum level of compentence before delivering the intervention in the trial.
Winnett et. al 2015 [15S] Design: Randomised Controlled Trial	To assess the efficacy of theory-based maintenance approaches varying by dose for persistently performing resistance training (RT) with the hypothesis that a	Older adults (50–69 years), with a BMI of 25–39.9 kg/m2, all fitting pre-diabetes criteria.	N=170 enrolled in the initial 3 month phase. After the 3-month phase (N=159) were randomized to one of two conditions:	No definition	♦**Design**: (i) The study design was based on a theory.(ii) The dose was set out before the intervention commenced.(iii) Specification of provider credentials. (iv)Ensured they had sufficient power to detect treatment effects. (v) Wave system of recruitment to match personnel. ♦**Training:** (i) The certificates of providers were checked before training. (ii) All providers received standardised initial training. (iii) Providers were given manuals. (iv) On-going supervision and feedback.

	higher-dose social cognitive theory (SCT) approach would produce greater RT adherence than lower-dose Standard.		SCT (intervention ; N=79), or Standard (control; N=80).		♦**Delivery**: (i) The providers were given session scripts to follow prompts for which points in the session to emphasise. (ii) Post session checklists were completed (iii) Sessions were randomly checked by the research team. (iv) Participants anonymously rated provider technical and interpersonal skills. (v) Sessions were supervised to maintain enthusiasm. (vi) Contamination was limited by using separate manuals for each condition and assigning any individuals with links to different groups. (vii) Participants reported on unsupervised sessions and were given feedback depending on group allocation. ♦**Receipt**: (i) All participants received hands on training and feedback for 3 months during the intervention. (ii) All participants can perform each exercise with proper form, range of motion, and degree of effort at the end of the intervention period. (ii) All participants were provided with a manual and instructions for the maintenance phase. ♦**Enactment**: (i) Participants completed transition sessions for unsupervised training; by the end of the transition participants were able to plan and report workouts.
Wyatt et. al 2015 [16S] Design: Randomised Controlled Trial	To examine the components of intervention fidelity, as put forth by the Treatment Fidelity	Breast cancer survivors	N=183	Fidelity consists of the measures taken to assure that an intervention is carried out as prescribed by the intervention protocol. (Radziewicz	♦**Dose parameters** A clear description of the dose to be given was set out and described from the start. ♦**Training** (i) Providers were trained to train participants in self-delivery by a certified acupuncturist. (ii) Demonstrations were conducted and the participants had to reach

	Workgroup of the Behaviour Change Consortium at the National Institutes for Health (NIH-BCC Workgroup), within an ongoing acupressure study of breast cancer survivors with persistent cancer-related fatigue.			et al. 2009, Calsyn 2000, Wyatt 2010)	>/95% on the Acupressure Fidelity Form. (iii) Providers also received refresher training at a predefined point. (iv) Participant training: The correct technique was demonstrated to the participants. (vi) Participants then carried out the acupuncture with feedback and had to reach >/95% on the on the Acupuncture Fidelity Form before completing training. (v) Participants were also given an instruction manual and DVD. ♦**Self-delivery:** (i) Participants had a 3 week follow up session after the initial training to evaluate their technique. (ii) Feedback was provided to the participants and participants were required again to meet >/95% on the Acupressure Fidelity Form. (iii) The participants logged their sessions throughout the intervention and are given contact information in case questions arise during the intervention period. ♦**Intervention receipt:** (i) Participant logs were examined to evaluate receipt. (ii) Attrition rates were also used to examine the number of participants who completed the entire protocol. ♦**Enactment:** (i) This is on-going and not reported.
Avery et al. 2014 [17S] Design: Protocol for an open pilot study and	To conduct an open pilot study to establish the acceptability, feasibility and fidelity of the multifaceted	Adults diagnosed with non-insulin dependent type 2 diabetes for	N=200 (n=100; intervention and n=100; control)	With so few primary studies explicitly utilising treatment fidelity strategies to monitor and improve training for care providers (where	♦Consultations were videotaped (20-40%) and review appointments to assess adherence to and appropriate use of components of the intervention using a specifically developed checklist. Efforts will be made to record an equal number of consultations at each intervention time point.

external pilot randomised control trial	intervention movement as medicine for type 2 diabetes in the primary care setting.	a minimum of 2 years.		training is offered), or to monitor the delivery of interventions to patients in practice, it is difficult to establish whether the interventions are being delivered as intended. Therefore it becomes impossible to decipher whether reported outcomes are a function of the intervention or 'non-intervention' factors (Resnick et al. 2005a).	♦The results of assessment of the delivery will be used to inform future training.
Baquero et. al 2014[18S] Design: Process Evaluation of a Randomised Control Trial	To describe a comprehensive process evaluation of an efficacious store-based intervention that increased store customers' fruit and vegetable consumption.	Shops That Serve Latino Immigrants in North Carolina; target population the customers of the sops	Four small-medium tiendas (n=2 intervention and n=2 control)	Fidelity was defined as the extent to which each of the intervention activities were delivered as intended, including the integrity and quality of the Intervention implementation. (No reference)	♦Process evaluation approach: Feedback was received from the employees and managers regarding the training. ♦Measured the amount of time managers and employees spent in training. ♦There was an assessment of how the funding for structural changes was allocated and which structural changes took place. ♦Assessed the degree to which the marketing campaign took place/was implemented; food demonstrations took place as planned and print materials were distributed as planned
Bryant et. al 2014[19S]	To describe the processes in training physical	People over the age of 50 with	N=222 (Strengtheni ng exercise	Treatment fidelity, a term that refers to the consistent and reliable	♦The quality of delivery of the intervention was assessed against previously standardised criteria from audio recordings of sessions (randomly

Design: Three arm randomised control trial	therapists: (1) to deliver a standardized pain coping skills treatment and (2) to evaluate the effectiveness of that training.	knee osteoarthritis	n=75, pain coping skills training (PCST) n=74, strengthening exercises and PCST n=73)	delivery of interventions (Bellg et al. 2004).	selected 10% of recordings from both groups). Three measures of session's quality were used: (1) Adherence to each specific element (2) Physical therapist competence (3) Evaluated for demonstrated used of therapeutic skills.
Dewing et al. 2014[20S] Design: Comparison post training to follow up (1[illegible]s)	To determine the impact of refresher training and supervision on counsellors' proficiency in the intervention	Lay counsellors carrying out function related to health care	N=39	No definition.	♦Audio recordings were taken from two time points (1) recording per provider at time point 1 and up to 3 at time point (2) and rated with a specifically developed coding sheet as to whether they adhered to the protocol and according to (a) the clarity with which the counsellor explained the scale to the patient and (b) whether the counsellor was specific about the behaviour that they were asking the patient to rate themselves on. ♦Researchers also judged the quality of action plans agreed upon according to whether they appeared to have the potential to address the patient's adherence barrier or not.
Dyas et. al 2014[21S] Design: Qualitative study embedded in a pilot	To investigate treatment fidelity of an educational intervention delivered to general practice (GP) teams; designed to improve the primary care	Patients suffering from insomnia and general practice teams (GPs and practice nurses)	10 participants (n=6 patients, n=4 practitioners)	Treatment fidelity has been defined as the degree to which a treatment or intervention is delivered to participants as intended (Bruckenthal and Broderick 2009).	♦Short telephone interviews were conducted with patients and practitioners who participated in the intervention to explore any breaches in fidelity. The conditions that they wanted to explore were set out a priori: (i) adherence to the intervention (ii) Patient receipt and understanding of the intervention (iii) Patient enactment. ♦The interviews were analysed to identify barriers and facilitators to these components of

cluster randomised control trial	management of insomnia.				intervention fidelity and to understand why breaches in fidelity occurred.
Hardeman et. al 2014 [22S] Design: Randomised controlled trial	To develop a reliable coding frame for recorded consultations, and to describe the delivery and receipt of intervention and standard care components to understand how the intervention might have worked.	Patients with type 2 diabetes	N=211 (n=126; intervention. N=85; control)	Trial evaluations rarely include an assessment of the extent to which interventions are delivered and received as planned (fidelity), to what extent they are adapted, and what this means for long-term implementation and impact in routine clinical practice (Bellg et al. 2004).	♦Training was standardised for all nurses delivering the intervention. ♦The providers practiced intervention techniques during training. ♦All consultations were audio recorded and assessed adherence to scripted protocol. ♦Feedback was provided to nurses following listening to the audio recordings.
Kulwa et. al 2014 [23S] Design: Study protocol of a cluster randomised controlled trial	To implement and evaluate the effectiveness of a nutrition education package in improving infant and young child feeding practices, dietary adequacy and growth	Infants aged 6 months and their parents	Not applicable: Study protocol	Assess whether the intervention activities are implemented as planned (i.e. fidelity). (No reference)	♦Activity logs: A record will be kept of the amount of sessions conducted (with participants, health care workers, families and nutrition counsellors) and materials distributed. ♦Supervisory reports: a review of the providers' workbooks will be conducted to evaluate completeness, validity of documen information, referrals, appointmen missed. ♦Registration forms will record the number of community based nutrition counsellors trained and the number of health facility staff sensitised.

					♦Pre-post test scores will be used to assess skill acquisition of providers was assessed before and after training. ♦Evaluation forms: To evaluate the quality of the training sessions was evaluated ♦Structured observations: Providers' interpersonal skills during home visits, use of intervention material, problem solving and confidence will be assessed.
Lorencatto et. al 2014[24S] Design: Fidelity assessment of a Cross-sectional study	To evaluate the fidelity of telephone-delivered behavioural support from the UK's national quitline service, using coded component behaviour change techniques (BCT's).	Smokers seeking cessation advice	75 sessions were audio recorded	Fidelity refers to the extent to which core intervention components are delivered as intended distinguished from how components are delivered such as quality (Borrelli 2011).	♦Identified BCTs in the treatment manual. ♦Audio recorded sessions (75) and assessed if the BCTs specified in the treatment manual were delivered in practice
McKenzie et. al 2014 [25S] Design: Randomised feasibility trial	To examine (1) operational feasibility of the programme; (2) participants' views of the programme; and (3) speech intelligibility, communication effectiveness and	Patients at least 3 months post stroke with no co-existing neurological condition and having dysarthria, with	N=39 (n = 20, control and n = 19 intervention) .	No definition	♦Monitored sessions to assess if the delivery was consistent with the protocol in relation to time distribution within sessions, therapy materials, and appropriate inclusion of modelling, practice opportunities, feedback, reinforcement, verbal reward, review, response correction, encouragement, communication maximization strategies, and achievement of 80% threshold success on stimulus sets before progression.

	tongue and lip movement at four points.	articulatory imprecision.			
Neilson et. al 2014[26S] Design: Qualitative design	To investigate physical therapists' experiences and perspectives of a cognitive-behavioural informed training and intervention process as part of a randomized controlled trial involving adults with knee osteoarthritis.	Physical therapists	Eight physical therapists trained to deliver the programme	No definition.	♦Initial training was followed by additional formal mentoring and instruction, role playing, and performance feedback from a psychologist at each trial site over the course of 3 to 6 months ♦Audio recordings of training were reviewed by a psychologist to assess if the physical therapist was competent in delivering the intervention. ♦Audio recordings of the PT- patient interaction were reviewed throughout the study and feedback was provided to the PT from a psychologist.
Presseau et. al 2014[27S] Design: Two-armed cluster randomised controlled trial	To conduct a cluster randomised controlled trial to evaluate the effectiveness and costs of a theory-based behaviour change intervention targeting general practitioners (GPs) and nurses, to support	GP's, practice nurses/nurse practitioners, and healthcare assistants working in the study practices actively engaged in	Not applicable: study protocol (will be conducted in 44 GP practices)	Investigate whether the intervention was delivered as designed. (No reference)	♦**Delivery:** (i) Provider's will complete questionnaire-based facilitator report of delivery completed after each session. (ii) Consultations will be audio recorded and analysed using a checklist of the behavioural change technique (BCTs) to be delivered at each consultation and whether the duration of the BCT changes over the course of the delivery period and between facilitators. (iii) Post intervention feedback forms will be distributed post intervention. ♦**Receipt and enactment** will be assessed through brief questionnaires delivered with the post intervention process evaluation.

	improvement in the provision of high-quality care for people with type 2 diabetes.	providing diabetes care.			
Robbins et. al 2014[28S] Design: Process evaluation of a pilot intervention	To evaluate the reach, dose and fidelity of Guys Only Activity for Life (GOAL), a physical activity intervention programme and motivational interviewing techniques for 6th and 7th grade boys.	6th and 7th grade boys (USA).	2 schools (n=1; intervention and n=1 control. N=30 boys from each school)	Quality of intervention delivery or the extent to which the intervention was implemented in the manner and spirit in which it was intended (Linnan and Steckler 2002).	♦Observed delivery of a physical activity intervention using a survey adapted from other studies to assess delivery of the use of strategies to motivate, encourage or support the boys to increase their moderate vigorous physical activity. This was scored on a 4 point likert scale. ♦Motivational interviewing sessions were audio recorded. Two researchers were trained to evaluate these recordings and the Motivational Interviewing Code 3.1.1 was used to determine adherence to motivational interviewing. To further evaluate the delivery of the motivational interviewing the degree to which they assessed adherence to the underlying theory was assessed using a 4 point likert scale.
Van Schijindel-Speet et. al 2014[29S] Design: Process Evaluation of a Randomised Control trial	To describe the results of the process evaluation of a physical activity (PA) programme for people with intellectual disabilities (ID).	Adults (age 44+) with intellectual disabilities.	Eighty-one participants and 65 controls (age 44+) with mild or moderate ID.	Fidelity-implementation of the intervention (Baranowski et al. 2000, Saunders et al. 2005, Glasgow 2006).	♦PA instructors reported directly to the researcher if a PA programme session was cancelled.

Washington et. al 2014[30S] Design: Cohort	To advance the discussion of treatment fidelity in social and behavioural intervention research by analysing fidelity in an intervention study conducted within participating long term care settings of the Collaborative Studies of Long-Term Care.	Family members of relative in nursing homes and residential care/assisted living settings and staff of these settings.	N=6 nursing homes and n= 18 residential care settings (intervention). Control (not applicable).	The extent to which an intervention is delivered as intended (Glasgow et al. 1999).	♦Study designed so as participants would receive a full dose of the intervention by attending all workshops. ♦Reminders were sent for upcoming workshops to encourage attendance and attendance at each workshop was recorded. ♦Participants were given a certificate of achievement upon completion and staff were given continuing education credits. ♦All supplies were made available to participants to ensure they could successfully perform these activities. ♦Follow up contact was made by the interventionist to see if a service plan had been created and if it was being followed as planned.
Almas et. al 2013[31S] Design: Group non-randomised cluster trial	To determine the feasibility and effectiveness of recruiting and retaining female preadolescents aged 9–11 years to both study arms and of implementing a 20-week school-based physical activity programme with the intervention	Girls aged 9-11. In Karachi.	N=280 (n=131 intervention group and n=149; control group)	Treatment fidelity was defined as the proportion of planned physical activity sessions actually held in the intervention group out of those planned. (No reference)	♦Recorded the amount of sessions delivered and reasons why session weren't delivered.

	group (treatment fidelity).				
Bach et al. 2013[32S] Design: Feasibility and acceptability cohort study	To determine the feasibility and acceptability to physical therapists and patients of a cognitive behavioural pain self-management programme.	Physical therapy cohort and pain patient cohort	N=31 physical therapists and n=21 patients.	No definition.	♦A portion of consultations were audio recorded and scored with a predefined checklist. Fifty per cent were scored independently by two raters and the remainder were scored by a single rater.
Barber et al. 2013[33S] Design: Protocol for a pilot cluster randomised controlled trial	To describe the protocol for PIP Pre-schoolers in the Playground; a pilot cluster randomised control trial (RCT) of an outdoor playground-based physical activity intervention for children aged 18 months to 4 years; to assess the feasibility of conducting a full scale cluster RCT.	Parents and their children aged 18 months to 4 years old	Not applicable: Study protocol	No definition.	♦At the end of each session the trainer will record whether the training was delivered as intended. The providers being trained will also complete a short evaluation form at the end of each session to ensure skill acquisition. ♦3 Sessions at each intervention site will be observed and scored with a standardised form. ♦At the end of each session the provider will complete a form reporting whether the session was provided, the number attending and the activities provided.
Benzo et. al 2013[34S]	To develop and test an intervention that	COPD patients hospitalised	N=11	No definition.	♦**Study design** (i) strategies were utilised to ensure the treatment dose was the same within condition. (ii) Training provided to deal with

Design: Pilot testing of intervention	focused on patient engagement for behaviour change in important aspects of the daily life in severe chronic obstructive pulmonary disease patients that can have impact on their perception of health and hospitalizations and that could be integrated with pulmonary rehabilitation.	for exacerbation			different types of patients equally. (iii) All sessions recorded, with external monitoring. (iv) Interventionist self-monitoring of treatment delivery each session ♦**Training** (i) Standardised training, both materials and personnel. (ii) Training used recorded session review and role-play to help account for patient differences and interventionist differences in implementation style. (iii) Interventionists were scored with pilot patients using session checklist. (iv) Interventionists used self-assessment with checklists. (v) Feedback was provided from recorded intervention session with interventionist. (vi) Interventionists asked to identify desired training topics to assist with intervention skill acquisition. (vii) Regular booster training sessions were provided. (viii) Reviewed sessions where the interventionist or fidelity monitor identified the session deviated from protocol. (ix) Regular debriefing meetings were held and training was centred according to needs, background, and clinical experience of the clinicians. ♦**Delivery**: (i) Delivery was standardised as an intervention protocol was used to guide each session. (ii) Recorded sessions and assessed them with a behavioural checklist completed by the fidelity Monitor. (iii) Providers completed a self-assessment checklist following each session. (iv) Case conferences were held in which

					providers discussed cases and trainer reviews skills and strategies.
Bergstrom et. al 2013 [35S] Design: Cluster randomised controlled trial	To investigate the effectiveness of a novel and complex intervention to improve diet and physical activity, targeting both caregivers and residents, in community residences for people with intellectual disabilities (ID).	Adults with ID and their caregivers	N=172 (N=90 ; intervention and n=80; control)	Intervention fidelity, defined as the extent to which a programme adheres to its programme theory (Fraser 2009).	♦Providers' activity at network meetings was recorded and they were assigned points based on this. ♦Measured number of sessions held for residents (participants) and assigned points as per same.
Branscum et. al 2013 [36S] Design: Process Evaluation of a Group randomized controlled design.	To report the results of a comprehensive process evaluation for the "Comics for Health" program, a childhood obesity prevention intervention implemented at 12 after-school programs.	Children and adolescents	N=71 (n=37; control group, n=34; intervention group)	The extent to which the intervention was delivered as planned. (No reference)	♦Intervention sessions were observed with a structured tally sheet (author has established the readability and validity before use); which included a list of major tasks the provider was to complete to assess if the intervention was delivered as intended the provider also completed a separate checklist for self-check.
Gabbay et. al 2013 [37S]	To determine if the addition of	Adults aged 18-75	N=545 (n=232;contr	No definition.	♦Sessions were audio recorded and evaluated using a reliable and validated tool Behaviour

Design: 2-year randomized controlled pragmatic trial	nurse case managers trained in motivational interviewing to usual care would result in improved outcomes over two years in patients with type 2 diabetes who are at high risk for cardiovascular complications.	with type 2 diabetes who were at high risk for complications.	ol and n=313; intervention)		Change Counselling Index to evaluate the delivery of the motivational interviewing. ♦Feedback was given regularly based on these evaluations but diminished as the providers became more proficient. ♦The providers and two investigators met to review study progress biweekly or more frequently if needed.
Goode et. al 2013 [38S] Design: Evaluation of intervention delivered in the context of a cluster randomised control trial	To highlight what is optimally involved on the part of researchers to drive and facilitate successful health behaviour intervention implementation and evaluation in dissemination contexts.	Patients with type 2 diabetes or hypertension	Not reported (implementation paper)	Intervention fidelity or the extent to which a program is delivered as intended, or adheres to essential elements of the original evidence-based intervention (Fraser 2009).	♦All providers were trained ♦Developed manuals for the providers and participants ♦Number of calls completed ♦Duration of calls completed ♦Participant use of program materials and satisfaction.
Lorencatto et. al 2013[39S] Design: Observational study	To evaluate a method for assessing fidelity of behavioural support; assess fidelity of delivery in two	Smoking cessation	N=21 recordings	Fidelity of an intervention refers to the extent to which interventions are delivered as intended, with adherence to specifications in	♦A proportion of consultations were obtained audio recorded. ♦Treatment manuals were coded according to an established taxonomy of BCTs. ♦Transcripts of the audio recordings were then coded according to the BCTs as per the

	English Stop-Smoking Services; and compare the extent of fidelity according to session types, duration, individual practitioners, and component behaviour change techniques (BCTs).			intervention manuals (Bellg et al. 2004, Borrelli 2011).	treatment manual to assess delivery of the intervention.
Mars et al 2013[40S] Design: Fidelity assessment of a two-arm randomised controlled trial intervention	To demonstrate development and testing of tools, procedures to monitor and assess the intervention integrity of a complex intervention for chronic pain.	Chronic musculoskeletal pain	N=703 (n=403 intervention; n=300 control)	Intervention fidelity is defined as the use of methodological strategies to monitor and enhance the reliability and validity of behavioural programmes (Bellg et al. 2004).	♦All courses were audio recordings and fidelity was assessed under 3 domains. (i) Adherence: a component specific measure was designed to assess the delivery of key elements as described in the intervention facilitator's manual. (ii) Competence: A generic competence measure was designed to determine the extent to which the providers created an environment in which participants could share their experiences and learn new skills. (iii) Overall impression: Another measure was designed to reflect the extent to which the aims and objectives of the component were achieved and how the material was received in the group.
Pfeiffer et. al 2013[41S] Design: Study	To observe the effects of a multi-component intervention on physical activity,	3-5 year old children	Not applicable: Study protocol	No definition.	♦Direct observations and ratings of PA opportunities provided by teachers and children's PA during those opportunities (OSRAC-P, observational system for recording physical activity in children- preschool version).

protocol for a two-year randomized control trial (nested cohort design)	sedentary behaviour, and physical activity energy expenditure in 3-5 year-old children; identify factors that associate with change in those variables; and evaluate the process of implementing the multi-component intervention.				♦Teachers' self-reports of intervention completeness, fidelity measures; barriers to implementation and children's responsiveness to the intervention were obtained. ♦The site directors' self-reports of practices related to physical activity with interviews were obtained.
Poston et. al 2013[42S] Design: Pilot randomised control trial	To determine if a complex intervention in obese pregnant women leads to anticipated changes in diet and physical activity behaviours and to refine the intervention protocol through process evaluation of intervention fidelity.	Obese pregnant women	N=183 (intervention ; n=94, control; n=89)	If each component of the complex intervention was provided as intended. (No reference)	♦Health trainers (providers) completed audio diaries (130 recordings) reflecting on the fidelity and feasibility of the intervention delivery. ♦Measured if the intervention package was delivered as intended i.e. all consultations. ♦Group size was recorded. .

Scobbie et. al 2013[43S] Design: Process Evaluation	To examine the implementation, acceptability and perceived benefits of a goal planning and action planning framework in one community rehabilitation team with people recovering from stroke.	Stroke patients and health professionals (physiotherapists, occupational therapists, dietician, nurse and speech and language)	N=8 patients N=8 health professionals (n=2 occupational therapists; n=2 physiotherapist; n=1 dietician; n=1 nurse and n=2 speech and language therapists.)	No definition	♦Provider case notes for participants were reviewed to assess if the intervention was implemented as planned.
Sears et. al 2013[44S] Design: Mulitple baseline design	To examine the feasibility and potential efficacy of adapting the prevent-teach-reinforce model for use with two families of young children with autism spectrum disorders.	Autism spectrum disorder	N=2 boys (4 and 6 years old) and their families	No definition	♦Implementation fidelity was calculated as percentage based on the total number of correct intervention steps implemented divided by the total number of steps that were applicable. ♦Parents delivering the intervention were trained on a 1:1 basis. They practiced implementing the steps until they could implement them with 90% accuracy. If the implementation scores fell below 80% at any point then additional coaching sessions were given. ♦The researchers reviewed video recordings with the parents and provided feedback.
Seo et. al 2013[45S] Design: Prospective	To evaluate if the HEROES Initiative; a school-based childhood obesity	4th–8th grades from elementary and middle	N=1091 (intervention only)	No definition	♦Interviewed school wellness co-ordinators, principals and cafeteria managers (on two occasions). ♦Observed the school environment assessing 9 specific domains relating to the intervention.

longitudinal design	prevention program based on the U. S. Centers for Disease Control and Prevention coordinated school health approach was able to effectively increase physical activity among elementary and middle school students who were exposed to the program for 18 months and to determine student and school-level predictors of success.	schools in Southern Indiana.			Scores were awarded based on this observation to assess whether the intervention was being delivered as intended.
Sternfield et. al 2013[46S] Design: Randomised controlled 3 by 2 factorial trial	To describe the rationale for the 3 by 2 study design, to discuss issues relevant to intervention-specific methodology and implementation, and to present data on	Post-menopausal women	N=355	No definition	♦Training was standardised and all providers were given a study manual. ♦During training mock yoga classes were conducted and all yoga instructors were given training CDs, DVDs and handbooks. ♦Exercise trainers were given detailed written instructions regarding prescription and progression of exercises. ♦The importance of strict adherence to the intervention protocol was emphasised repeatedly during trainings.

	recruitment, eligibility, and baseline characteristics				♦Fidelity of the yoga intervention was monitored through the completion of a form by an unblended staff member and the yoga instructors communicated weekly via email with the Seattle investigators to describe how classes were proceeding and if they had any questions or concerns. ♦Fidelity of the exercise intervention was monitored whereby one session a week was observed to ensure fidelity to the protocol using a quality control checklist. The exercise trainers completed a log to ensure the prescribed dose was being achieved. Exercise trainers, supervisors and experts in exercise training had regular conference calls to resolve any issues. ♦For both exercise and yoga, a list of "Frequently Asked Questions" was compiled and distributed monthly to ensure a standardized approach to any issues that arose that had not been specified in the protocol. In addition, site visits were conducted.
Wilner et. al 2013 [47S]	To evaluate the impact of a staff-delivered manualised cognitive behaviour therapy anger management intervention on reported anger among people with mild to			Therefore, treatment integrity or fidelity checks are needed, in order to be able to monitor the extent to which treatments are delivered appropriately (Moncher and Prinz 1991)	♦Fidelity was monitored by direct observation. A pair of observers attended selected sessions to monitor fidelity. ♦An existing checklist (CTS-Psy66) was adapted to monitor the fidelity of the intervention. Additionally monitors made global ratings on a ten point's scale of fidelity to the manual, group process, principles of CBT and a single overall rating. Observers then compared their results and discussed any differences to come to a consensus decision.

	moderate intellectual disabilities, and anger coping skills, aggression, mental health, quality of life and costs of health and social care; factors that influence outcome; and the experience of service users, lay therapists and service managers.				
Zheng et. al 2013[48S] Design: Randomised Control Trial	To design a system to support the fidelity of intervention delivery and efficient capture of qualitative and quantitative process data for a telephone-delivered behavioural change counselling intervention to increase physical activity and	Patients with advacned knee osteo arthritis post total knee replacemen t	Not reported	No definition	♦On screen documentation and prompts guided the providers through the consultation to deliver all components.

	function after total knee replacement surgery.				
Bodde et. al 2012[49S] Design: Formative and process evaluation strategies	To conduct a formative and process evaluation of the Promoting Health through Physical Activity Knowledge and Skills curriculum which was designed to increase the physical activity knowledge and skills of adults with intellectual disabilities.	Adults with intellectual disabilities.	N=21 (n=21 women and n=21 men)	No definition.	♦Providers were instructed to use an exact script. ♦On four random occasions the provider's adherence to the script was assessed.
Broekhuizen et. al 2012[50S] Design: Parallel randomised control trial	To evaluate the efficacy of an individualised tailored lifestyle intervention on physical activity, dietary intake, smoking and compliance on statin therapy in people with Familial	Adults with familial hypercholesterolemia	N=340 (n=181; intervention and n=159 control)	No definition.	It was assessed whether face-to-face counselling sessions were implemented as planned according to motivational interviewing (MI) guidelines (i.e. MI fidelity) was assessed by two MI experts, following the Motivational Interviewing Treatment Integrity code (MITI 3.1.1.)

	Hypercholesterolemia				
Brookman-Frazee et. al 2012[51S] Design: Pilot single armed intervention	To examine the feasibility of training community mental health therapists to deliver a package of evidence-based practice strategies to children with autism spectrum disorders and challenging behaviours, and their parents with routine services.	Children with autism spectrum disorder and community based mental health therapists.	N=13 community based mental health therapists and n=13 children with ASD	No definition	Three methods were used to measure fidelity: ♦Treatment planning phase fidelity: treatment planning forms were reviewed by intervention developers to assess to adherence to key elements. ♦The active treatment phase session fidelity treatment: treatment sessions were observed. This included ratings on 3 required within sessions therapist behaviours. Each therapist behaviour had associated therapist strategies which guided a rating on a 4 point Likert scale. ♦ Therapists completed a web based survey after the training period. For each intervention the step therapists rated the extent to whic completed each step.
Cate et. al 2012[52S] Design: Protocol for a randomised control trial	To determine whether additional education and advice about glaucoma using a Behaviour Change Counselling intervention, improves adherence with topical anti-glaucomatous therapy.	People with glaucoma	Not applicable: Study protocol	No definition	♦The providers information provision was assessed in terms of adherence to the BCC template and consultation style assessed using Behavioural Change Counselling Index via a video recorded session with an actor patient. The video recorded role-play session were independently reviewed according to the BBCI criteria by the Motivational Interviewing (MI) coach and two experts in MI independent to the research study. ♦Individualised written feedback was provided to the providers.

Cowan and Devine 2012[53S] Design: Process evaluation of a quasi-experimental design	To evaluate the implementation of a controlled, 6 week environmental and educational intervention to improve dietary intake and body composition, and to study the association if implementation fidelity with diet and body composition outcomes.	Residents of drug treatment facilities	N=107	No definition	♦Food environment changes were assessed through direct observations of reviewed shopping lists, weekly menus and food inventories in each of the six facilities, and observed meals.
Faulkner et. al 2012 [54S] Design: Fidelity assessment of a feasibility intervention.	To describe the components of intervention fidelity, the complexity of measurement when conducting research with youth and families, and strategies for measuring intervention fidelity.	Adolescents with type one or type 2 diabetes.	N=50	Intervention fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioural Interventions (Bellg et al. 2004).	♦**Study Design:** The intervention was built on a strong theoretical foundation for exploring behaviour change with an evidence support it. Treatment dose and inte length were set out from the start. ♦**Training of providers:** (i) A detailed study manual was developed. (ii) Providers learnt the study protocol and proper clinical etiquette for recruitment and professional communication with participants.(iii) Role play was also done so research assistants (RAs) could become more familiar with recruitment scripts, use of equipment and conducting home visits and fidelity checklists for the personalised exercise programme.

					♦**Delivery:** (i) Fidelity checklists were completed at each home visit. (ii) The study team met weekly to discuss home visits fidelity checks, accelerometer downloads and any questions from the RAs could also be addressed. ♦**Receipt:** Feedback was obtained from the participants about refinement of the intervention to further enhance sustainability of exercises. ♦**Enactment:** Accelerometer recordings over the 16 weeks served as a measure of enactment.
Gallanter et. al 2012[55S] Design: Retrospectiv e pre-post design	To further explore the effectiveness of in-home parent child interaction therapy with a diverse sample of parent–child dyads by using data from a child maltreatment prevention program.	Families/pa rents at risk of maltreating children	N=83 clinical records of families were reviewed.	No definition	♦The supervisor monitored two sessions per year to ensure consistency with the protocol.
Heideman et. al 2012 [56S] Design: Pilot study of single arm intervention	To assess the fidelity, feasibility and acceptability of a prevention program for overweight first degree relatives of type 2 diabetes patients intervention prior	Individuals with a family history of type 2 diabetes.	N=21	Asses the fidelity (where intervention modules delivered as intended). (No reference)	♦All the sessions were observed and findings recorded on a specifically developed checklist based. Observers checked whether all modules were delivered and all objectives for participants were covered; observers reported on the engagement of participants by looking at interactions between trainer and participants and among participants; and observed whether the sessions were delivered in a constructive, empowering atmosphere.

	to starting the randomized controlled trial.				
Hildebrand et al 2012 [57S] Design: Fidelity assessment of randomised control trial	To describe the development of methods to train and supervise therapists to attain adequate treatment fidelity in a treatment development project involving a novel occupational therapy and physical therapy based intervention.	Older adults who are in short term skilled nursing facilities (SNF) following a disabling medical event	N=26 (n=14; intervention group, n=12 control)	Treatment fidelity comprises two key aspects: 1) treatment integrity, that is, demonstrating that therapists carry out the intervention with adequate levels of adherence and competence to the treatment model or protocol; and 2) treatment differentiation, that is, ensuring that the experimental intervention condition differs from a control condition (i.e., showing much higher adherence and competence to the treatment model (Perepletchikova and Kazdin 2005, Sharpless and Barber 2009)	♦All sessions were videotaped and rated with a checklist specifically developed to rate treatment adherence and competence that quantified behaviours consistent with the intervention. Observations for fidelity ratings were done 12 months after therapists training while they were receiving on going supervision.
Hollands et. al 2012[58S]	To test the hypothesis that communicating	Smokers who were first degree	N=497 (n=251; intervention;	No definition	♦Reviewed a random selection of audiotapes to assess fidelity to the protocol.

Design: Parallel group, cluster randomised controlled trial	risk of developing Crohn's disease based on genotype and that stopping smoking can reduce this risk motivates behaviour change among smokers at familial risk.	relatives of probands with Crohn's disease	n=246 control)		
Irvine et al 2012 [59S] Design: Process Evaluation of text message delivered intervention	To assesses the utility of novel techniques for process evaluation involving no face to face contact.	Men aged 25 to 44 years, who lived in areas of high social deprivation and had regular episodes of heavy drinking.	N=67 (n=34 ; Intervention n=33;control)	The fidelity of delivery of the intervention (the extent to which the text messages were delivered as intended). (No reference)	♦Recorded how many text messages were delivered.
Knowlden and Sharma 2012[60S] Design: A Feasibility and Efficacy Randomized Controlled Trial (protocol)	To evaluate the efficacy of the Enabling Mothers to Prevent Childhood Obesity Through Web-Based Education and Reciprocal Determinism program, an	Mothers with children aged 4-6.	Not applicable: Study protocol	Implementation process evaluation is a specific type of process evaluation that examines fidelity of program delivery. Assessment of implementation allows the researchers to ensure the program was delivered to the	♦Log-in codes and tracking data will be used to assess whether the website and subsequent module materials were accessed. The date and duration of activity will be logged to a whether audio-visuals were viewed an adequate time was spent to complete eacn activity. ♦Online, interactive worksheets and module quizzes will have forced-response validation to gauge transference of information.

	Internet-based, theory-driven intervention for preventing childhood overweight and obesity.			participants in the prescribed fashion. Failure to evaluate program fidelity can make it difficult to confirm whether non-significant program outcomes were due to ineffective intervention components or inadequate transference of intervention deliverables. (No reference)	♦Reminder emails will be sent to assess promotion. ♦At the completion of the intervention, respondents will be requested to complete an open-ended questionnaire regarding acceptability and perceived usefulness of the program. Additionally, data regarding maintenance of confidentiality will be collected.
Llewellyn et al 2012[61S] Design: Multicentre randomised control trial (protocol)	To examine the impact of motivational interviewing augmented with information provision and behavioural skills building, over and above usual care, on risky sexual behaviour in men	Men who have sex with men (MSM) prescribe PEP for HIV following sexual exposure	Not applicable: Study protocol.	Assessing the fidelity of the treatment is an important component of successful research dissemination. (No reference.)	♦Study design has ensured there will be the same dose between conditions. ♦Reduction of differences within treatments will be ensured by the use of one trained interventionist. ♦Interventionist skill acquisition and minimising 'drift' in interventionist skills will be minimised by the development and use of a treatment manual with the provision of feedback. ♦Audiotape sessions and coded using a validated instrument to ensure delivery and provide feedback to the provider.

	who have sex with men prescribed post exposure prophylaxis (PEP) after potential sexual exposure. A secondary aim of this research is to examine the impact of the intervention on adherence to PEP.				♦Provider to complete a checklist after each session to remind him to include appropriate skills and content. ♦An advisory board will be used to monitor whether treatment protocol has been adhered to during recruitment and intervention period.
McCurry et. al 2012[62S] Design: Pilot randomised control trial	To investigate the feasibility of implementing a Sleep Education Program (SEP) for improving sleep in an adult family home residents with dementia and the relative efficacy of SEP compared to usual care (control) in a pilot randomised control trial	Adult family home (AFH) caregivers and residents with dementia and sleep disturbance s	N=84 (n=37 AFH caregivers; n=47 residents)	No definition	♦**Delivery**: Providers were given a written manual with materials for each session. A checklist was completed after each session indicating which treatment topics had been covered. All sessions audiotaped and reviewed by investigator who provided feedback re adherence to treatment protocol. ♦**Receipt:** Staff-caregiver attendance at the sessions and clinical impressions were rated by a trainer after each session. The trainer also recorded whether staff- caregivers were able to identify specific behaviours and develop plans based on these behaviours for the week. ♦**Enactment:** The trainer reviewed homework at every session, rated homework compliance and assisted staff-caregivers in problem-solving.
Moore et. al 2012[63S]	To examine implementers views on	Exercise professiona ls and area	N=37 (n=27 exercise professionals	No definition	♦Recordings of consultations were assessed using Behaviour Change Counselling Index.

Design: A Mixed methods study	delivering motivational interviewing (MI) within an exercise referral scheme and consistency of consultations with MI before and after a 2 day workshop.	coordinators delivering the Welsh National Exercise Referral Scheme.	and n=10 coordinators)		♦Coders then estimated whether professionals spoke for more than half, about half or less than half of the consultation time. ♦Pre training to fidelity MI was compared with post training fidelity.
Morganstrern et. al 2012[64S] Design: Pilot 3 armed intervention study	To test the causal role of key hypothesized active ingredients and mechanisms of change within motivational interviewing (MI) in reducing drinking.	Adults between 18-65 with alcohol use disorder	N=89 (N=29 motivational interviewing (MI); n=30 SOMI (Spirit Only MI); n=30 SC (Self Change)	No definition	♦**Training**: Videotapes of practice cases were reviewed to ensure fidelity to the protocol. Performance was then reviewed and therapists were required to meet a certain level of fidelity before treating participants. ♦**Delivery** (i) 30% percentage of sessions were observed and assessed for fidelity to MI using the MI integrity code 3.0 to assess fidelity from the observer perspective. (ii) The modified version of the therapy session report was used to assess for fidelity from the client perspective.
Robbins et. al 2012[65S] Design: Two-group pretest posttest quasi-experimental study	To describe the methodology and findings related to the treatment fidelity of face-to-face motivational interviewing sessions involving middle school girls and a school nurse to help the girls increase their	Middle school girls (10-14 years)	N=37	Developing, implementing, and evaluating a treatment fidelity plan is a time-consuming, but important, process for researchers to ensure that an intervention has been implemented as intended and accurately tested (Bellg et al. 2004).	♦**Study design:** The underlying theory is stated and how it was congruent with clinical process. ♦**Training:** An additional provider was trained to allow for potential setbacks. Training was standardised and the providers were given an intervention manual. The providers did role play and were given feedback as part of the training. ♦**Delivery and receipt:** The providers kept logs of the sessions. All sessions were audiotaped and some were randomly selected for assessment.

	moderate to vigorous physical activity.				

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APPENDIX 22

SUMMARY TABLE OF RESULTS OF ASSESSMENT OF STUDIES INCLUDED IN SYSTEMATIC REVIEW BY WILSON ET AL. 2014 WITH THE TIDIER CHECKLIST

Appendix 22 Summary table of results of assessment of studies included in systematic review by Wilson et al. 2014 with the TIDieR checklist

Study	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	
Nguyen et al. 2008	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N	N	9/11
Moy et al. 2008	Y	Y	Y	Y	N	Y	Y	Y	Y	N/A	N	N	8/11
Tabaket al. 2014	Y	Y	N	Y	Y	Y	Y	Y	Y	N/A	Y	Y	10/11
Effing et al. 2011	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N	N	9/11
Varga et al. 2007	Y	Y	N	Y	N	Y	N	Y	Y	N/A	N	N	6/11
Berry et al. 2003	Y	Y	Y	Y	N	Y	Y	Y	Y	N/A	Y	Y	10/11
Hospes et al. 2009	Y	Y	Y	Y	Y	N	N	Y	N	N/A	N	N	6/11
Nguyen et al. 2013	Y	Y	N	Y	Y	Y	Y	Y	Y	N/A	N	N	8/11
Wewel et al. 2008	N	Y	Y	Y	N	Y	Y	Y	Y	N/A	N	N	7/11
Moy et al. 2012	Y	Y	Y	Y	N	Y	Y	Y	Y	N/A	N	N	8/11
Behnke et al. 2005	Y	Y	Y	Y	N	N	N	Y	Y	N/A	N	N	6/11
Steele et al. 2007	Y	Y	N	N	N	Y	N	Y	N/A	N/A	N	N	4/10

Nguyen et al. 2009	Y	Y	N	Y	Y	Y	N	Y	Y	N/A	N	N	7/11
Probst et al. 2011	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N	N	9/11
Pomidori et al. 2012	N	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N	N	8/11
Plegysulos et al. 2013	Y	Y	Y	Y	N	Y	Y	N	Y	N/A	N	N	7/11
Nguyen et al. 2005	Y	Y	N	Y	Y	Y	Y	Y	Y	N/A	N	N	8/11
Breyer et al. 2010	Y	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N	N	9/11
Berry et al. 2010	Y	Y	N	Y	N	Y	N	Y	Y	N/A	Y	Y	8/11
DeBlok et al. 2006	N	Y	N	Y	N	N	N	Y	Y	N/A	N	N	4/11
N=YES	17	20	12	19	10	17	13	19	18	N/A	3	3	

APPENDIX 23

BLANK BORRELLI 2011 CHECKLIST

Study design

1. **Provider information about treatment dose in the intervention condition**

A.Length of contact (minutes)	
B.Number of contacts	
C.Content of treatment	
D.Duration of contact over time	

2. **Provide information about treatment dose in the comparison condition**

A.Length of contact (minutes)	
B.Number of contacts	
C.Content of treatment	
D.Duration of contact over time	
E.Method to ensure dose equivalent between conditions	
F.Method to ensure dose is equivalent for participants within conditions	

3. **Specification of provider credentials that are needed:**

4. **Theoretical model upon which the intervention is based is clearly articulated**

A.The active ingredients are specified and incorporated in the intervention	
B.Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines	
C.Plan to ensure that the measures reflect the hypothesise theoretical constructs/mechanisms of action	

5. **Potential confounders that limit the ability to make conclusions at the end of the trial are identified**.

6. **Plan to address possible setbacks in implementation (i.e. back-up systems or providers)**

Training

1. Description of how providers will be trained (manual of training procedures)	
2. Standardisation of provider training (especially if multiple waves of training are needed for multiple groups of providers)	
3. Assessment of provider skill acquisition	
4. Assessment and monitoring of provider skill maintenance over time	
5. Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori	
6. At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g. ensure that providers find the intervention acceptable, credible and potentially efficacious)	
7. There is a training plan that takes into account trainees different education and experience and learning styles	

Delivery

1. Method ensure that the content of the intervention is delivered as specified	
2. Method to ensure the dose of the intervention is delivered as specified	
3. Mechanism to assess if the provider actually adhere to the intervention plan	
4. Assessment of nonspecific treatment affects	
5. Use of treatment manual	
6. There is a plan for the assessment whether or not the active ingredient was delivered	
7. There is a plan for the assessment of whether or not the proscribed	

components were delivered (e.g. components that are unnecessary or unhelpful)	
8. There is a plan for how contamination between conditions will be prevented	
9. There is a priori specification of treatment fidelity (e.g. providers adhere to >80% of components)	

Receipt

1. There is an assessment of the degree to which participants understand the intervention.	
2. There are specification strategies that will be used to improve participant comprehension of the intervention.	
3. The participants' ability to perform the intervention skills will be assessed during the intervention process.	
4. A strategy will be used to improve subject performance of intervention skills during the intervention period	
5. Multicultural factors considered in the development and delivery of the intervention	

Enactment

1. Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.	
2. A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.	

APPENDIX 24

PULMONARY REHABILITATION CHECK FORM FOR ALL SITES INCLUDED IN THE LIVELY COPD PROJECT

Pulmonary Rehabilitation check form for all sites included in the LIVELY COPD project

Site:		**Confirmed: date and person**
Contact person **- Name** **-Position**		
Contact Details **- Telephone** **- Email**		
No. of PR progress (number of programs running at any one time) **Setting (e.g. hospital)** **Rolling/Set**		
Duration **Location (e.g. physiotherapy gym)** **Frequency** **Days and Times** **Education Sessions (days)** **Exercise Class (days)** **Attendance record kept (please circle if a record is kept of one or both)**	Education / Exercise	
Usual education sessions and health professional delivering them		

APPENDIX 25

EVALUATION OF TRAINING PROVIDED FOR DELIVERY OF PHYSICAL ACTIVITY INTERVENTION - PROVIDER FEEDBACK EVALUATION QUESTIONNAIRE

Evaluation of Training Provided for Delivery of Physical Activity Intervention (PAI)

1. The training prior to delivering the intervention was adequate to prepare me to start delivering the physical activity intervention.

Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly Agree ☐

2. On-going training was regular enough to help me adhere to the agreed PAI protocol (this refers to both the training sessions and the weekly mentoring phone calls).

Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly Agree ☐

3. The training accounted for my individual learning styles, experience and education.

Strongly disagree ☐ Disagree ☐ Neutral ☐ Agree ☐ Strongly Agree ☐

4. Any positive/negative comments or thoughts with regard to the training provided so far for the delivery of this intervention:

5. Do you have suggestions on how the training for delivering this intervention could be improved?

APPENDIX 30

AMENDED DELIVERY CHECKLISTS DEVELOPED SPECIFICALLY FOR THE ASSESSMENT OF FIDELITY OF THE LIVELY PAI

Appendix 30- Amended delivery checklist

Consultation 1

Participant number:_____

Introduction (defined as a general introduction i.e. provider introducing self) ☐

Report on patient's health state and record any AEs ☐

Explain goal of the programme ☐

Mention general benefits of PA ☐

Familiarise patient with pedometer ☐

Do 20 step test ☐

Explain step diary ☐

'Managing Breathlessness' topic ☐

Arrange next appointment ☐

BCS checklist Consultation 1

Participant number:_____

Item	Component	Delivered (✓,X,?)	Comments
2	Provide information on consequences of behaviour in general and for the individual (pros & cons) of being more active (any risks of not being active).		
3	Disease specific education		

5	Training in use of pedometer (including 20 step test) and completion of 7 day diary		
20	Materials manual this relates to the LIVELY patient manual and LWWCOPD booklet for PR		

Consultation 2
Participant number:_____

Introduction defined as a general introduction between the practitioner and patient ☐

Assess if any AEs Report on patients health state and record any AEs ☐

Remind the patient of the goal of the programme ☐

Re-affirm PA levels ☐

Discuss the benefits of PA ☐

Set general goal (SMART) ☐

Note any problems with pedometer ☐

Record steps for the familiarisation week ☐

Do self-efficacy walk ☐

Set step goal for week ☐

Complete Action & Coping Plan ☐

Any Barriers discussed ☐

Assess patient confidence level ☐

Arrange next appointment ☐

BCS checklist Consultation 2

Participant number:_____

Item	Component	Delivered (✓,X,?)	Comments
1	Setting an overall walking (or functional) goal e.g. walking to sisters house or walking into town every day as a result of increased step counts/physical activity		
2	Provide information on consequences of behaviour in general and for the individual (pros & cons) of being more active (any risks of not being active) **Recap on the benefits of PA to this patient by referring to previous consultations and additional resources.** ***Think about benefits patient has obtained or consequences of activity specific to this patient.***		

4	Discuss the barriers to physical activity		
6	(a) Use of pedometer steps in self efficacy walk to set step goal (b) Use 7 day pedometer steps to set step goal		
7	Build self-efficacy focusing patients attention on where they have been able to do well and focus on any achievement		
8	Demonstrate appropriate walking pace during self-effiacy walk and BORG rating		
9	Plan behaviour using action/coping plan		
11	Record daily steps with pedometer		
17	clinician encourages social support-so walking with family friends or walking to meet somebody etc		
20	Materials manual LIVELY patient manual (including diary) and LWWCOPD booklet		

Consultations 3-11

Participant number:_____

Introduction (defined as a general introduction i.e provider introducing self) ☐

Report on patient's health state & record any AEs ☐

Patient progress reviewed ☐

Review overall (SMART) goal (appointment 6 only) ☐

New goal set & inserted into diary ☐

Action plan and coping plan completed ☐

Barriers discussed ☐

Confidence levels with new goal assessed ☐

Next appointment arranged ☐

BCS checklist Consultations 3-11
Participant number:_____

Item	Component	Delivered (✓,X,?)	Comments
1	**REVIEW (CONSULTATION 6 ONLY)** Setting an overall walking (or functional) goal e.g. walking to sisters house or walking into town every day as a result of increased step counts/physical activity		
2	Provide information on consequences of behaviour in general and for the individual (pros and cons) of being more active (any risks of not being active) **Recap on the benefits of PA to this patient by referring to previous consultations and additional resources.** ***Think about benefits patient has obtained or consequences of activity specific to this patient.***		
4	Discuss barriers to PA		

6	(a) Use of pedometer steps in self-efficacy walk to set step goal (b) Use 7 day pedometer steps to set step goal		
7	Build self-efficacy focusing the patients attention on where they have been able to do well and focus on any achievement		
9	Plan behaviour using action/coping plan		
11	Record steps with pedometer		
13	R/v planned and actual walking behaviour each week with clinician by reviewing diary and pedometer daily step count and provide feedback		
14	Review if goal met, not met or partially met		
15	Reward success or effort		
17	Clinician encourages social support-so walking with family or friends or walking to meet somebody etc…		
20	Materials manual i.e. LIVELY patient manual (Includes diary) and LLWCOPD manual		

Consultation 5

Participant number:_____

Introduction (defined as a general introduction i.e. provider introducing self) ☐

Report on patient's health state & record any AEs ☐

Patient progress reviewed ☐

New goal set & inserted into diary ☐

Action plan and coping plan completed ☐

Barriers discussed ☐

Confidence levels with new goal assessed ☐

Educational component covered ☐

Next appointment arranged ☐

BCS checklist Consultation 5
Participant number:_____

Item	Component	Delivered (✓,X,?)	Comments
2	Provide information on consequences of behaviour in general and for the individual (pros and cons) of being more active (any risks of not being active) **Recap on the benefits of PA to this patient by referring to previous consultations and additional resources.** ***Think about benefits patient has obtained or consequences of activity specific to this patient.***		
3	Disease specific education		
4	Discuss barriers to PA		

6	a. Use of pedometer steps in self-efficacy walk to set step goal b. Use 7 day pedometer steps to set step goal		
7	Build self-efficacy confidence focusing patients attention on where they have been able to do well and on achievements		
9	Plan behaviour using action/coping plan		
11	Record steps with pedometer		
13	R/v planned and actual walking behaviour each week with clinician by reviewing diary and pedometer daily step count and provide feedback		
14	Review if goal met, partially met or not met		
15	Reward success or effort		
17	Clinician encourages social support-so walking with family or friends or walking to meet somebody etc…		
20	Materials manual i.e. LIVELY manual (includes diary) and LWWCOPD booklet		

Consultation 12

Participant number:_____

Introduction (defined as general introduction)	☐
Report on patient's health state & record any AEs	☐
Patient progress reviewed	☐
Step count inserted into chart	☐
Summary of 12 week steps inserted	☐
Review Progress from week 1	☐
Benefits of walking reinforced	☐
Personal goal reviewed	☐
Discuss maintenance strategies	☐
Summary of barriers & successful strategies inserted	☐
Other relapse prevention discussed	☐
Relapse due to COPD Exacerbation advice given	☐
Plan for continuing maintenance discussed	☐
Resources for additional walking given	☐
Complete PAI patient progress summary	☐

BCS checklist Consultation 12
Participant number:_____

Item	Component	Delivered (✓,X,?)	Comment
1	**REVIEW** Setting an overall walking (or functional) goal e.g. walking to sisters house or walking into town every day as a result of increased step counts/physical activity		
2	Provide information of behaviour in general and for the individual (pros and cons) of being more active (any risks of not being active)		
4	Discuss barriers to PA		
7	Build self-efficacy focusing the patients attention on where they have been able to do well and focus on achievement		

13	Review planned and actual walking behaviour each week with clinician by reviewing diary and pedometer daily step count		
14	Review if goal met, not met or partially met		
15	Reward success or effort		
16	Certificate of achievement		
17	Clinician encourages social support-so walking with family friends or walking to meet somebody etc.		
18	Week 12 refer back, also review past sucess and also in terms of successful strategies		
19	Plan for relapse prevention		
20	Materials manual i.e. LIVELY patient manual (includes diary) and LLWCOPD manual		

APPENDIX 31

AMENDED RECEIPT CHECKLIST DEVELOPED SPECIFICALLY FOR THE ASSESSMENT OF FIDELITY OF THE LIVEY PAI

Participant number:_____

Item 1:There is an assessment of the degree to which the patient understands the intervention

Familirisation week: Demonstration of patient using pedometer and 7 day recall ☐

Item 2: There are specification strategies that will be used to improve participant comprehension of the intervention

Appointment	Focus	Received	Comment
1	General benefits of exercise discussed		
	Educational component delivered		
2	Reaffirm PA levels and benefits		
3-11	Recap on benefits of PA	3 4 5 6 7 8 9 10 11	
5	Educational component		
1-2	Familiarisation week	2	
1	20 step test		
2	Self-efficacy walk		
1-12	Weekly contact (review how	1 2 3 4 5 6 7 8 9 10 11 12	

	many face-face and over the phone)													
2-11	Action/coping plan	3	4	5	6	7	8	9	10	11				
3-12	Goal setting for step count with the pedometer	3	4	5	6	7	8	9	10	11	12			

Item 3: The participants' ability to perform the intervention skills will be assessed during the intervention process

Appointment	Focus	Received										Comment
3-12	R/v progress-assessing whether step targets were met	3	4	5	6	7	8	9	10	11	12	
	Using tools: pedometer and diary	3	4	5	6	7	8	9	10	11	12	

Item 4: A strategy will be used to improve subject performance of intervention skills during the intervention period

Appointment	Focus		Comment
2	Set step goal		
	Complete action and coping plan		
	Assessment of confidence level		

	Stage of change and additional strategies											
3-11	Reset walking goal	3	4	5	6	7	8	9	10	11		
3-12	Revisit step target as per previous week	3	4	5	6	7	8	9	10	11	12	
3-12	Identify strategies from previous week that worked to do more walking	3	4	5	6	7	8	9	10	11	12	
3-11	Complete action and coping plan	3	4	5	6	7	8	9	10	11		
3-11	Confidence rating	3	4	5	6	7	8	9	10	11		

Item 5: Multicultural factors considered in the development of delivery of the intervention (notes from throughout the intervention)

Comments

APPENDIX 32

AMENDED ENACTMENT CHECKLIST DEVELOPED SPECIFICALLY FOR THE ASSESSMENT OF FIDELITY OF THE LIVELY PAI

Assessment of Enactment (Whether the participant applies the skills learned in treatment to his/her daily life between sessions)

Participant number_____

1. Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied **In LIVELY this relates to step counts and whether the participants meet their goals and the extent to which they followed the action plan**

Cons	Criteria	Comment
2	(i) Does the step diary match the 7 day pedometer recall	
3	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
4	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
5	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
6	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
7	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
8	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	

9	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
10	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
11	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	
12	(i) A review and a report on the participants step count is completed (ii) A review and report of whether the participant has met their goal is completed (iii) A review on the extent to which the participant followed their action plan is completed	

2. A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied **In LIVELY the strategy relates to a record of step counts from the pedometer each week**

Cons	Criteria	Comment
2	A step diary and pedometer have been provided for one week to allow the participant to familiarise themselves with	
3	A step count is recorded and reported.	
4	A step count is recorded and reported.	
5	A step count is recorded and reported	
6	A step count is recorded and reported.	
7	A step count is recorded and reported.	
8	A step count is recorded and reported.	
9	A step count is recorded and reported.	
10	A step count is recorded and reported.	
11	A step count is recorded and reported.	
12	A step count is recorded and reported.	

APPENDIX 34
SUMMARY OF AVAILABLE AUDIO RECORDINGS OF LIVELY PAI CONSULTATIONS

Table 1. Summary of available audio recordings per consultation from each provider

consultation	Number of recordings	Provider 1	Provider 2	Provider 3
1	7	3	2	2
2	7	3	2	2
3	4	2	2	0
4	6	4	1	1
5	7	5	1	1
6	6	4	1	1
7	8	5	2	1
8	7	2	2	3
9	7	3	1	3
10	6	2	0	3
11	8	4	2	2
12	8	5	2	1

Total consultations conducted: **221**

Consultations done pre fidelity protocol: **N=75 (34%)**

Consultations not recorded due to participant declining: **N=12 (5.4%)**

Consultations missed due changes in protocol: **N=36 (6.3%)**

Consultations missing due to various recorder problems: **N=18 (8.1%)**

Consultations with available recordings: **N= 80 (36.2%)**